January 2023

# CPSC Staff Statement<sup>1</sup> on Boise State University's, "Crib Bumper Product Characterization and Testing"

The report titled, "Crib Bumper Product Characterization and Testing," presents the findings of research conducted by Boise State University, under Task Order No. 61320620F1021, Infant Suffocation Research on Crib Bumpers, for the indefinite-delivery, indefinite-quantity (IDIQ) Contract No. 61320620D0002 for infant biomechanics and suffocation research and consultancy services.

This research included a technical review of the appropriateness of the airflow requirement and test method specified in CPSC's 2020 proposed rule for crib bumpers/liners<sup>2</sup>; how thickness and firmness interact to determine the risk of facial occlusion from the crib bumpers conforming to the face; and the extent to which the presence of a crib bumper increases the ability of an infant to climb out of a crib. As part of this task order, the contractor performed firmness testing, airflow testing, CO<sub>2</sub> rebreathing testing, and simulated crib climb-out testing on sample crib bumpers and liners, and recommended revised requirements and improved test methods, as appropriate.

Due to the passage of the Safe Sleep for Babies Act of 2021, Pub. L. No. 117-126, which mandates that crib bumpers be considered a banned hazardous substance, the Commission terminated its rulemaking that proposed a product safety rule for crib bumpers/liners.<sup>3</sup> Nevertheless, this report provides CPSC valuable information regarding infant hazards and test methods.

<sup>&</sup>lt;sup>1</sup> 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.

<sup>&</sup>lt;sup>2</sup> Boniface, D. E., & Smith, T. P. (2019). Staff Briefing Package: Staff's Draft Notice of Proposed Rulemaking for Crib Bumpers under the Danny Keysar Child Product Safety Notification Act. Available: https://www.cpsc.gov/s3fs-public/Proposed Rule - Safety Standard for Crib Bumpers-Liners Under the Danny ... 0.pdf.

<sup>&</sup>lt;sup>3</sup> 87 FR 44307 (July 26, 2022).

# Crib Bumper Product Characterization and Testing

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Research conducted from September 2020 to May 2021.

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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<sub>2</sub> Carbon Dioxide

CPSC Consumer Product Safety Commission

H<sub>2</sub>O Water

IDI In-Depth Investigation

O<sub>2</sub> Oxygen

# 1. Introduction

The purpose of this portion of the project was to conduct a breadth of tests on crib bumpers, to interpret the results in the context of suffocation or climb-out risk, and to brainstorm new testing concepts that might differentiate between products that may have inherent risks versus those which may not. We used information gained from the literature reviews we conducted and the IDIs we reviewed (Appendix A) to inform justifications for tests, development of new tests, and interpretation of test results. We also reviewed and evaluated the proposed rule put forth by the United States Consumer Product Safety Commission (CPSC) regarding crib bumpers, and we made recommendations on the suitability of tests in evaluating safety of crib bumpers.

We first consider that an infant suffocation incident can occur in various ways: through nasal occlusion or obstruction, airflow restriction, decrease in oxygen (O<sub>2</sub>), increase in carbon dioxide (CO<sub>2</sub>), or a combination of these scenarios. We focused our efforts related to crib bumper suffocation on firmness, airflow, and rebreathing. We assume throughout this document that the safest crib scenario is a bare crib: one that features only a mattress with a thin cotton sheet. Accordingly, the safest "firmness" of a crib side can be considered a completely rigid material, like a wooden crib slat or solid panel. Similarly, without a crib bumper in place, airflow between the infant face and the side of the crib would not be inhibited by any other factors other than the crib design itself (slatted side or solid panel side, for example). Therefore, there is likely a threshold of one or both of these criteria (firmness and airflow) which can differentiate between products by suffocation hazard in the crib. The purpose of our suffocation-related testing is to understand how various crib bumpers perform under a gamut of tests related to firmness and airflow, and to quantify thresholds which may differentiate safe and unsafe products. We also designed and conducted a test related to climb-out scenarios which represent a different hazard related to crib bumpers.

We first selected and characterized products (2. Product Selection, Characterization, and Measurement), performed a gamut of suffocation-related testing (3. Firmness Testing, 4. Airflow Testing, 5. CO<sub>2</sub> Rebreathing Testing) and climb-out testing (6. Climb-out Testing). We also explored new and combination test methods and offer future areas of research to explore (7. Alternative and Advanced Methods, and 8. Future Studies). We summarize the document (9. Summary and Key Points), and list the references used (10. References). Most sections include Methods, Results, Discussion, and Recommendations regarding changes to CPSC's proposed rule.

# 2. Product Selection, Characterization, and Measurement

#### 2.1 Product Selection

The goal of product selection was to purchase products that represent the range of options within the product class. We conducted internet searches to find and purchase 20 different products that fell into the "crib bumper" or related category. Of these, we classified 13 as "traditional" crib bumpers, meaning they featured a fabric cover with some inner material and were designed to cover the inner side surface of an entire crib. These 13 traditional bumpers included: 3 that were marketed as "breathable," 1 that was purchased secondhand, 1 that was an artisan product purchased on an online marketplace, and 8 conventional crib bumpers. We classified the remaining 7 crib bumper-related products into 4 categories: 2 were "mesh" designs, meaning a mesh fabric with no internal filling; 1 was "braided"; 2 were "vertical," meaning they were designed to only cover crib slats; and 2 were "lounger" products, which have some qualities similar to traditional crib bumpers, but are stand-alone products that are not intended to attach to the crib in any way. Figure 1 depicts products representative of each of the 5 categories (traditional, mesh, braided, vertical, and lounger).



**Figure 1**: Categories of products tested with representative samples.

Appendix B details the manufacturer, product name, and purchase price of each product. For the purpose of this report, we assigned all products unique identifiers (S01 through S20), and manufacturer information was hidden throughout all of the testing. Appendix B also includes a photo of each product. We conducted measurements, characterization, and testing for all products in a random order. After products were selected, we characterized and measured each product, provided results, and discussed our findings.

# 2.2 Product Characterization and Measurement Methods

The measurements taken for all 20 products are detailed in Table 1. Products that included laundering instructions were washed and dried 3 times according to the manufacturer's instructions. For products that had multiple pieces, measurements were taken for the longest piece of the set.

**Table 1**: Measurements and characteristics with procedures and photos of a representative product.

Measurement	Procedure	Photos
Length	Product first stretched to full length and allowed to return to rest. Tape measure used to measure overall length of the longest piece in each set.	
Width	Tape measure used to measure width of product, which could also be considered the height of the product once installed onto a crib.	
Thickness	Analog caliper used to measure thickness of product under no force application.	
Mesh? (Y/N)	Whether the product featured mesh	
Attachment Method	Crib attachment method	
Number of Pieces	Total number of pieces in set	
Attachment	Whether attachment instructions were	
Instruction (Y/N)  Material	included with packaging  Product materials recorded from labels, packaging, or listing	
Cross-Sectional Photo	Piece of product, approximately 10 inches in length, was cut and photo taken of cross section	

#### 2.3 Product Characterization and Measurement Results

Table 2 shows the measurements and characteristics of all 20 products. Products with "(long)" and "(short)" in the length column indicate that the product had two representative sizes amongst all the pieces. For product S12, the inclusion of a base led to multiple measurements to fully characterize the product, with one measurement representing the overall product and one just of the base. Table 3 describes the material composition of each product if found on labels, packaging, and listing. Table 4 includes any relevant notes taken regarding the products during the characterization process.

**Table 2**: Sample measurements and characteristics.

Samples	Category	Length (cm)	Width (cm)	Thickness (cm)	Mesh	Attachment Method	No of pieces	Instructions
S01	Traditional	402	25	3.7	N	Ties	1	N
S02	Traditional	129 (long); 67 (short)	25	2.3	N	Ties	4	N
S03	Traditional - "Breathable"	132 (long); 69 (short)	24	1.2	N	Ties	4	N
S04	Traditional - "Breathable"	128 (long); 68 (short)	29	0.7	Y, not single layer	Ties	4	N
S05	Traditional	379	25	3.5	N	Ties	1	N
S06	Mesh	340 (long); 161 (short)	30	0.4	Υ	Ties + Hook and loop	2	Y
S07	Mesh	279 (long); 205 (short)	28	0.4	Y	Ties + Hook and loop	2	Y
S08	Braided	225	13	4.6	N	None	1	N
S09	Vertical	16	60	0.9 (with foam); 0.2 (w/o foam)	N	Zipper for wrapping around slat	2 (1/slat)	N
S10	Vertical	16	59	1.2 (with foam); 0.1 (w/o foam)	N	Zipper for wrapping around slat	2 (1/slat)	N
S11	Lounger	75	44	11.4 (at thickest side); 7.3 (at crease)	N	None	1	Y
S12	Lounger	80 (top pad); 71 (base)	45 (top); 39 (base)	13.1 (overall), 3.1 (base)	N	None	1	N
S13	Traditional	131 (long); 67 (short)	27	2.2	N	Ties	4	N
S14	Traditional	394	25	3.7	N	Ties	1	N
S15	Traditional - "Breathable"	93 (long); 59 (short)	21	0.7	N	Ties	4	N
S16	Traditional	252	16	2.3	N	Ties	1	N
S17	Traditional	198	30	1.3	Ν	Ties	1	N
S18	Traditional - Used	386	22	5.9	N	Ties	1	N
S19	Traditional - Handmade	178	32	2.1	N	Ties	1	N
S20	Traditional	121 (long); 65 (short)	26	4.8	N	Ties	4	N

Table 3: Composition of products as listed on product tags or packaging.

Samples	Material
S01	100% Cotton, Filling: 100% Polyester
S02	100% Cotton, Filling: 100% Polyester
S03	100% Poyester, Filling: 100% Polyester
S04	100% Poyester, Filling: 100% Polyester
S05	100% Cotton, Filling: 100% Polyester Fiber
S06	Soft 3D Mesh Fabric
S07	100% Polyester
S08	Cotton (from Amazon listing)
S09	Exterior: 100% Polyester, Interior: Poly-foam Insert lined with non-woven polypropylene
S10	Exterior: 100% Cotton, Interior: Poly-foam Insert lined with non-woven polypropylene
S11	100% Organic Cotton, Filling: 100% Polyester Fiber
S12	Cover Fabric: 100% Cotton, Tube Filling: Polyester Fibers, Pad: Polyester Padding, Inner Sleeve: 100%
S13	Cover Fabric: 100% Cotton; Filling: Resin treated polyester fiber 100%
S14	Cover Fabric: 100% Cotton; Filling: 100% Polyester Fiber
S15	100% Polyester
S16	Cover Fabric: 100% Cotton; Filling: Resin treated polyester fiber batting
S17	Cover Fabric: 100% Cotton; Filling: Porous microfiber
S18	100% Organic Cotton, Filling: 100% Polyester
S19	100% Linen (flax)
S20	100% cotton body; Gold satin for piping/ruffles

**Table 4**: Sample notes describing product set and other pertinent details.

Samples	Notes
S01	Variable thickness - product has quilting intermittently that reduce its thickness.
S02	Product in 4 pieces - 2 long pieces for long sides of crib, and 2 short pieces for short sides of crib.
S03	Product in 4 pieces - 2 long pieces for long sides of crib, and 2 short pieces for short sides of crib.
S04	Product in 4 pieces - 2 long pieces for long sides of crib, and 2 short pieces for short sides of crib; Product has mesh on the inside (baby facing) of the product, however the other side is solid fabric. Diamond pattern quilting.
S05	Variable thickness - product has quilting intermittently that reduce its thickness.
S06	Product in 2 pieces - 1 long piece for most of crib, 1 short piece; Product has no warning/identifier labels. Material is unknown - descibed as soft, 3D mesh fabric; Product has hook and loop attachment on either end and ties in the center. There are 2 different mesh patterns on either side/face.
S07	Product in 2 pieces - 1 long piece for most of crib, 1 short piece. Product has hook and loop attachment on either end and tie in the center. There are 2 different mesh patterns on either side/face.
S08	No warning labels. Material unknown. Washing and braiding instructions included.
S09	Product has plush, foam-like exterior, akin to felt. There are zippers on either long edge for attachment around slat. Product has no warning labels. Thickness measurements were taken twice, once on the side WITH the foam insert, and once on the side WITHOUT foam insert.
S10	There are zippers on either long edge for attachment around slat. Product has no warning labels. Thickness measurements were taken twice, once on the side WITH the foam insert, and once on the side WITHOUT foam insert.
S11	Variable thickness along edges due to seam in middle of shorter side. Unable to measure inner thickness due to design (see photos). Revers ble front/back.
S12	Separate tag says material is 71% Polyester F ber and 29% Polyester Fiber Batting. Cardboard insert included for storage. Thickness taken as max overall and max of base alone (see photos). Fabric lifted off base pad near ideal head location due to tubing.
S13	Product in 4 pieces - 2 long pieces for long sides of crib, and 2 short pieces for short sides of crib.
S14	Variable thickness - product has quilting intermittently that reduce its thickness.
S15	Product in 4 pieces - 2 long pieces for long sides of crib, and 2 short pieces for short sides of crib; Diamond pattern quilting similar to S04.
S16	Variable thickness - product has qjuilting intermittently that reduce its thickness, smallest width tested.
S17	No labels. Material found on vendor's listing. Random zipper that does not move.
S18	Variable thickness - product has quilting intermittently that reduce its thickness. Used so parts are frayed.
S19	Variable thickness - product has quilting intermittently that reduce its thickness; Handmade; No warning/material tags.
S20	Product in 4 pieces - 2 long pieces for long sides of crib, and 2 short pieces for short sides of crib. Looks used/dirty. Very uniform, almost solid. All pieces have removable foam pieces. Labels inside zipper.

#### 2.4 Product Characterization and Measurement Discussion

The products selected varied in material, composition, size, and design. The unloaded thickness of the traditional bumpers varied from 0.4 to 5.9 cm. Materials included polyester, cotton, linen, microfiber, and polyfoam. Installation instructions were lacking in most products, and product labeling was inconsistent or non-existent in many cases. Additionally, the term "breathable" was used to describe a few products, which, as far as we know, does not have a quantifiable meaning. It was unclear if foam materials used in products were open or closed cell foam. This distinction likely will influence airflow and rebreathing characteristics and could be considered in the future.

We did not perform the 7.3 Crib Bumper Liner Thickness test described in F1917-20. That test is pass/fail and also confounds thickness and firmness. We chose to measure an unloaded thickness and examine the data more robustly through additional testing.

#### 2.5 Product Characterization and Measurement Recommendations

Product composition, assembly instructions, and warning labels could be included with all products. However, as shown in Sections 3 and 4, labeling on the product may change the firmness or airflow characteristics, and therefore label material and location could be carefully considered. Terms such as "breathable" are undefined in the context of infant products, and consideration could be given if the term should be used to describe products until an objective test is designed to define the term in the context of infant breathing.

# 3. Firmness Testing

# 3.1 Firmness Testing Overview

Firmness testing has been used in other product classes to understand if a sleep product is firm enough to prevent a hazardous suffocation scenario. In the context of a crib bumper, a firm crib bumper would not allow for deformation of the product around an infant's nose and mouth and may be classified as safer than a product that conforms to an infant's face. The CPSC staff has proposed that crib bumpers and liners are tested using a custom firmness testing fixture at specified points along the bumper. The bumper is placed on a horizontal and rigid surface and may be secured to the surface using the crib bumper attachments to approximate the installation when secured on a crib side.

In this section, we tested bumpers and bumper-like products using the standard firmness testing methodology from Australian Standard/New Zealand Standard (AS/NZS) 8811.1:2013, adapted according to the specifications in the U.S. CPSC Proposed Rule (CPSC, 2020). Our interpretation of the standard allowed for two different test setups: (1) at a common set of locations on each crib bumper on a flat surface (representing a solid panel crib); and (2) at a common set of locations while each bumper was secured to a horizontal slatted crib. Furthermore, we developed a modified firmness fixture to represent the scenario of an infant face in contact with a bumper *between* crib slats, and we tested each product with this modified method. Results from all methods were compared and discussed.

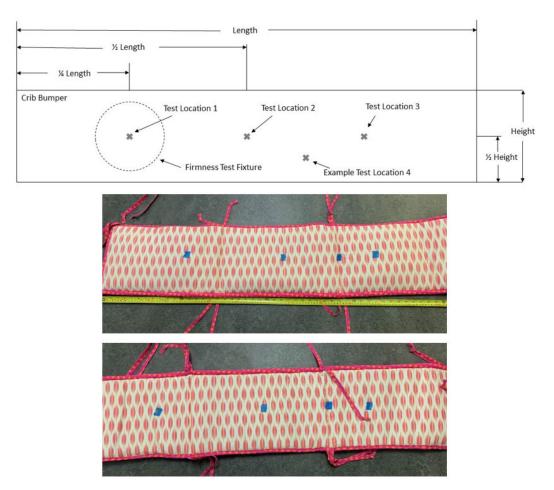
CPSC's proposed rule for crib bumpers does not require bumpers or liners under a certain thickness (*i.e.*, the thickness of the base plate of the test device) to undergo firmness testing. However, we chose to test all products regardless of thickness. The goal of our testing using these methods was to compare the CPSC staff's finding with our own results on a range of products classified as traditional, mesh, vertical, braided, and loungers, and to offer suggestions on how the method might be improved. We also tested a modified version of the standard to measure firmness *between* crib slats.

# 3.2 Firmness Testing Methods

## 3.2.1 Flat Surface with Unsecured Bumper Firmness Testing

Because we interpreted two different test methods allowed under the CPSC recommendation, we tested both methods. We first conducted firmness testing on all 20 products according to AS/NZS 8811.1:2013, with the bumper lying unsecured on a flat rigid surface, akin to a solid panel crib side. In this standard, a firmness fixture apparatus with a known weight allows for a pass/fail firmness test. We tested products, except for the lounger products S11 and S12, at the 8 locations indicated by AS/NZS

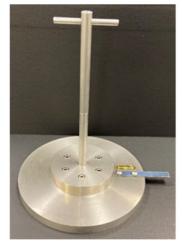
8811.1:2013. Locations 1 through 4 were located on the front of the product, with 1 through 3 being equidistant along the centerline and 4 being a subjective location of interest. Locations 5 through 8 reflected locations 1 through 4 on the back of the product, as shown in Figure 2.

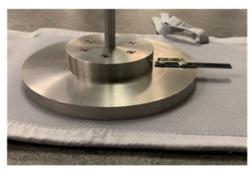


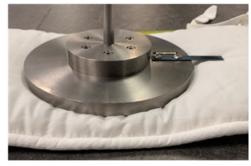
**Figure 2**: (Top) Standard Firmness Testing Locations on Flat Surface. Location 4 is subjective location of interest and varies. Locations 5-8 correspond respectively on the opposite side of product. (Middle) Example of firmness testing locations 1 through 4 on front of sample. (Bottom) Example of firmness testing location 5 through 8 on back of sample. Locations 4 and 8 were chosen based on location of a major crease or deformation in each product.

For the loungers S11 and S12, several additional locations of interest (beyond the locations required by AS/NZS 8811.1:2013) were tested. For product S11, there were 3 locations of interest on each side. Because of this, locations 1 through 6 represent the top of the product, while 7 through 12 represent the bottom. S12 had 3 locations of interest on the top side and none on the bottom. For this product, locations 1 through 6 represent the top of the product, while 7 through 9 represent the bottom. The team used the test fixture shown in Figure 3, with a mass of 5220 g, in accordance with AS/NZS 8811.1:2013. We

conducted all tests on a hard and flat surface with temperature and humidity conditions of  $70.9^{\circ} \pm 1.0^{\circ}$  F [70.0° to 72.0° F] and 20.2  $\pm$  4.0% [16.0 to 24.0%] respectively.



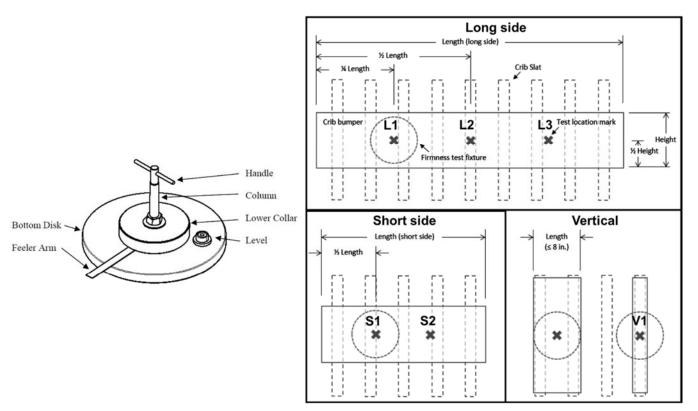




**Figure 3**: (Left) Firmness testing apparatus machined according to Australian/New Zealand Standard 8811.1:2013; (Middle) Example of passed test with feeler arm not in contact with product; (Right) Example of failed test with feeler arm in contact with product.

## 3.2.2 Slatted Crib with Secured Bumper Firmness Testing

Because the CPSC proposed rule notes that installation may be approximated by securing crib attachments during firmness testing, we interpreted this to mean the bumper could be first secured to the slatted crib, then the entire crib side with bumper would lie on a horizontal surface to undergo testing. Therefore, we also tested each product secured to a slatted crib side using the firmness fixture at predetermined locations relative to the length of the slatted crib, lying horizontally on the floor, according to our interpretation of the U.S. CPSC Proposed Rule (CPSC, 2020). The results from this testing are presented in Table 6.



**Figure 4**: Firmness test fixture (Left) and testing protocol (Right); design based on AS/NZS 8811.1:2013. We added prefixes and numbered testing locations which indicate L and S for the long and short sides of the product, respectively, and V for vertical (or vertically installed) products.

#### 3.2.3 Modified Firmness Testing Using Smaller Test Fixture

AS/NZ 8811.1:2013 was designed for horizontal sleep surfaces, and as such, may not represent the firmness of "crib bumper" products when *correctly* attached to a crib's slats and in the context of a baby's face in contact with it, particularly between slats. Because the firmness test fixture diameter is much larger than the allowable crib slat spacing, the firmness between the slats while the crib bumper in installed on a crib is unable to be assessed using the proposed method. Therefore, we used a new method to assess more accurately a crib bumper product's firmness *between* crib slats, as the firmness of the product in use within the crib environment with a baby's nose and mouth area may be pressed against the bumper *between* slats. The modified apparatus features a  $40 \pm 1$  mm diameter circular disk with a mass of  $200 \pm 1$  g (Figure 5). This new diameter represents 75% of the distance between slats of the crib possessed by the team and the mass was calculated to exert the same pressure as the original design. The mass proportions for the bottom disk and lower collar, and the height of the bottom disk remained the same as described in the original standard.

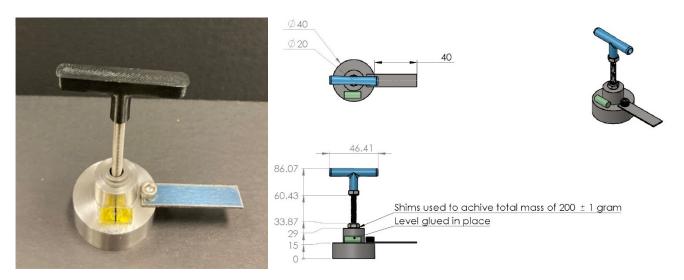


Figure 5: Modified firmness testing apparatus (L) and engineering drawing (R)

In this modified firmness test, traditional and mesh products were securely attached inside the crib. The crib was then rotated to rest on its side and slightly elevated off the ground, with the side containing the product nearer to the ground. The small firmness fixture was then placed on the product in locations according to Figure 4, and also between a pair of slats at a minimum of three locations with the feeler arm facing both along the length of the product and along the width (i.e., height when assembled on crib) of the product (Figure 6). These three new locations, shown in Figure 6, included the two slat spaces immediately adjacent to attachments on the crib's side, and a slat space equidistant from the two attachments with the largest space between them. For the adjacent slat spaces, corner attachments were not considered.

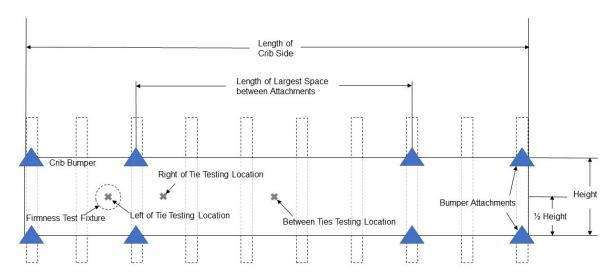


Figure 6: Testing locations for modified smaller firmness fixture for between slat testing.

Besides these three new locations shown in Figure 6, we also tested any other locations of interest. Vertical bumpers (S09 and S10) were not tested using this method since most testing locations were between slats and the device would fall between slats when bumpers were installed. The braided bumper (S08) and lounger products (S11 and S12) were also not tested because the fixture would not balance without significant manual adjustment which resulted in variability in results, limiting the reliability of the test. Also, considering this test method was developed primarily to test between-slat firmness, the braided bumper and lounger products were not the priority for testing using this method since neither type of product attaches directly to the crib. Figure 7 is a representative view of the testing setup.



**Figure 7**: (Left) Crib elevation setup, and (Right) modified firmness fixture placements between slats on rotated crib side.

# 3.3 Firmness Testing Results

Table 5 contains the overall results from the flat surface with unsecured bumper testing using the standard AS NZS 8811.1 fixture, Tables 6 and 7 contain the overall results from the slatted crib with secured bumper testing using the standard fixture and modified smaller fixture, and Tables 8 and 9 contain the overall results from the modified smaller fixture testing. Note that the testing on the Slatted Crib was not performed for the braided bumper (S08) or lounger (S11 and S12) products since the products don't have attachments for the crib sides.

**Table 5**: Firmness Testing Results using Standard-Sized Fixture on Flat Surface with Unsecured Bumpers at Locations in CPSC Proposed Rule (and shown in Figure 2) Green rows indicate the product passed at all testing locations. S04, S06, and S20 are the only products that passed all tests.

	Testing Location								
Samples	1	2	3	4	5	6	7	8	
S01	Fail	Fail	Fail	Fail	Fail	Fail	Fail	Fail	
S02-long	Pass	Fail	Pass	Pass	Pass	Pass	Pass	Pass	
S02-short	Pass	Fail	Pass	Pass	Pass	Pass	Pass	Pass	
S03-long	Fail	Fail	Fail	Fail	Fail	Fail	Fail	Fail	
S03-short	Fail	Fail	Fail	Fail	Fail	Fail	Fail	Fail	
S04-long	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	
S04-short	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	
S05	Fail	Fail	Fail	Fail	Fail	Fail	Fail	Fail	
S06-long	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	
S06-short	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	
S07-long	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	
S07-short	Pass	Pass	Pass	Pass	Fail	Pass	Pass	Pass	
S08	Pass	Pass	Pass	Pass	Pass	Pass	Fail	Pass	
S09	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	
S10	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	
S11*	Fail	Fail	Pass	Fail	Fail	Pass	Fail	Pass	
S12*	Fail	Pass	Pass	Fail	Fail	Pass	Pass	Pass	
S13-long	Pass	Fail	Pass	Pass	Pass	Pass	Fail	Pass	
S13-short	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	
S14	Fail	Fail	Fail	Fail	Fail	Fail	Fail	Fail	
S15-long	Pass	Fail	Fail	Pass	Fail	Fail	Pass	Pass	
S15-short	Pass	Pass	Pass	Fail	Pass	Pass	Pass	Pass	
S16	Fail	Fail	Fail	Fail	Fail	Fail	Fail	Fail	
S17	Fail	Pass	Fail	Pass	Fail	Pass	Pass	Pass	
S18	Fail	Fail	Fail	Fail	Fail	Fail	Fail	Fail	
S19	Pass	Fail							
S20-long	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	
S20-short	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	

<sup>\*</sup>S11 had four more testing locations (9 through 12) that resulted in a 'Pass' at location 9 and 'Fails' everywhere else. Similarly, S12 had one extra testing location that resulted in a 'Fail' condition.

**Table 6**: Firmness Testing Results using Standard-Sized Fixture on Products Secured to Slatted Crib at locations described in Figure 4

	Testing Location									
	Long	g Side of	Crib	Short Side of Crib Ver						
Sample	L1	L2	L3	S1	S2	V1				
S01	Fail	Fail	Fail	Fail	Fail					
S02	Pass	Pass	Pass	Pass	Pass					
S03	Pass	Pass	Fail	Fail	Fail					
S04	Pass	Pass	Pass	Pass	Pass					
S05	Fail	Fail	Fail	Fail	Fail					
S06	Pass	Pass	Pass	Pass	Pass					
S07	Pass	Pass	Pass	Pass	Pass					
S09						Pass				
S10						Pass				
S13	Pass	Fail	Pass	Pass	Pass					
S14	Fail	Fail	Fail	Fail	Fail					
S15	Pass	Pass	Pass	Pass	Pass					
S16	Fail	Fail	Fail	Fail	Fail					
S17	Fail	Pass	Pass	Fail	Fail					
S18	Fail	Fail	Fail	Fail	Fail					
S19	Pass	Pass	Fail	Fail	Fail					
S20	Pass	Pass	Pass	Pass	Pass					

**Table 7**: Firmness Testing Results using Modified Small Fixture at common Locations Described in Figure 4.

	Testing Location									
	Lon	g Side of	Crib	Short Side of Crib Vertica						
Sample	L1	L2	L3	<b>S1</b>	S2	V1				
S01	Fail	Pass	Pass	Fail	Fail					
S02	Pass	Pass	Pass	Pass	Pass					
S03	Fail	Pass	Fail	Pass	Pass					
S04	Pass	Pass	Pass	Pass	Pass					
S05	Fail	Fail	Pass	Pass	Pass					
S06	Pass	Pass	Pass	Pass	Pass					
S07	Pass	Pass	Pass	Pass	Fail					
S09						Pass				
S10						Pass				
S13	Pass	Pass	Pass	Pass	Pass					
S14	Fail	Fail	Fail	Pass	Fail					
S15	Fail	Pass	Pass	Pass	Pass					
S16	Pass	Fail	Fail	Fail	Fail					
S17	Pass	Fail	Pass	Fail	Pass					
S18	Pass	Fail	Fail	Pass	Fail					
S19	Fail	Fail	Pass	Pass	Fail					
S20	Pass	Pass	Pass	Pass	Pass					

**Table 8**: Firmness Testing Results using Modified Smaller Fixture at Locations Between Slats (Figure 6)

	Testing Location									
	Feeler Arn	n Along Leng	th of Product	Feeler Arm Along Height of Product						
Samples	Left of Tie	Right of Tie	<b>Between Ties</b>	Left of Tie	Right of Tie	<b>Between Ties</b>				
S01	Pass	Fail	Pass	Fail	Pass	Pass				
S02	Pass	Pass	Pass	Pass	Pass	Pass				
S03	Fail	Fail	Fail	Fail	Pass	Fail				
S04	Pass	Pass	Pass	Pass	Pass	Pass				
S05	Pass	Pass	Fail	Pass	Pass	Pass				
S06	Pass	Pass	Pass	Pass	Pass	Pass				
S07	Pass	Pass	Pass	Pass	Pass	Pass				
S13	Pass	Pass	Pass	Pass	Pass	Pass				
S14	Pass	Fail	Pass	Pass	Pass	Pass				
S15	Pass	Fail	Pass	Pass	Pass	Pass				
S16	Fail	Fail	Pass	Fail	Fail	Fail				
S17	Fail	Pass	Fail	Pass	Pass	Pass				
<b>S18</b>	Pass	Fail	Fail	Pass	Pass	Pass				
S19	Pass	Fail	Fail	Fail	Fail	Pass				
S20	Pass	Pass	Pass	Pass	Pass	Pass				

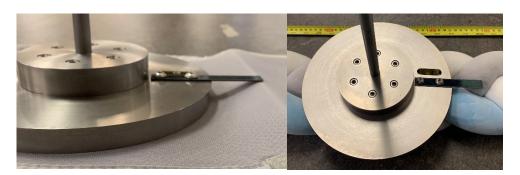
Table 9: Firmness Testing Results using Modified Smaller Fixture at Locations of Interest

Samples	Location	Result
S01	Quilting - along length	Fail
S01	Quilting - along height	Fail
S04	End of Product, next to corner slat	Fail
S06	Hook and Loop Attachment - right of slat, along length	Fail
S06	Hook and Loop Attachment - left of slat, along length	Fail
S06	Hook and Loop Attachment - left of slat, along height	Pass
S07	On Warning Label - along length	Pass
S07	On Warning Label - along height	Pass
S07	Off Warning Label - along height	Fail
S07	Off Warning Label - along height	Pass
S08	At 3-way intersection of braid - along length	Pass
S08	At 3-way intersection of braid - along length	Pass
S08	At 2-way intersection of braid - along height	Pass
S08	At 2-way intersection of braid - along height	Pass

### 3.4 Firmness Testing Discussion

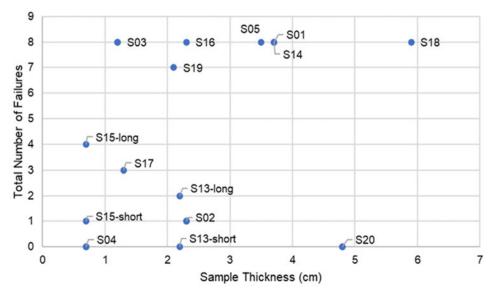
Some of the products possessed significant deformations from packaging and storage that were noticeable even after products were washed, dried, shaken, or laid out on a flat surface for several hours. This led to failures on products, such as S07 (Figure 8-left), that may not necessarily reflect *only* the firmness of the product but rather a combination of firmness and deformation of the product that may not be present when the product is installed in a crib. However, if the product were installed loosely onto a crib in a way that allows such deformation, and the material of the product did not allow for adequate airflow, a scenario where the product conforms around the infant's face even due to a packaging deformation is still a potentially hazardous scenario, and this firmness testing may elucidate a facial conformity scenario as evidenced by S07.

Furthermore, the firmness testing apparatus was unstable when tested on the braided product (S08, Figure 8-right) and the loungers (S11 and S12) due to the uneven support provided by these products. In such cases, the orientation of the firmness testing fixture base was adjusted gently until the base was horizontal while resting in accordance with the CPSC proposed rule.



**Figure 8**: (Left) Failure in S07 due to significant folding deformation. (Right) Firmness tester area overhanging width of product S08.

In general, the products in the mesh and vertical categories passed the firmness tests. The lounger and braided product categories were difficult to test using this method without adjusting the orientation and holding the device in place to accommodate balancing; this testing method may require additional consideration to ensure repeatable results if used for lounger or braided products due to the curvature of the products. The traditional bumper category was easy to test using this method and showed variability among products. Figure 9 shows a plot of the number of failures (of 8 tested locations) vs. unloaded thickness of the traditional bumpers during the flat surface testing. There is no apparent relationship between firmness and thickness of these products. However, most traditional bumpers failed the firmness test. The exceptions are discussed below.



**Figure 9**: Relationship between sample thickness and number of failures of firmness tests for traditional bumpers on a flat surface (Table 5). Both the long and short pieces from the bumper sets of products S02, S03, S04, and S20 exhibited the same number of failures so are only listed once.

A few traditional style bumpers passed all firmness tests. S20 features a unique design of a thick foam interior (4.8 cm). Observationally, the firm product did not deform in the same way as most traditional bumpers with polyester filling or batting did, and the lack of deformation during testing resulted in no failures in either test method. Product S13 featured a thicker outer material similar to canvas that differed from most other traditional bumpers. This material likely prevented deformation of the bumper more than those with thinner single-layer cotton exteriors. Product S04 was one of the thinnest traditional bumpers and passed every firmness test, likely because the product was thin (0.7 cm) compared to the height of the feeler arm on the testing device (1.5 cm).

It appears that firmness, as defined in these test methods, is dependent upon the material selection (internal filling material and density, and external cover material) rather than thickness alone, particularly when considering products > 1 cm thick where results were quite varied. This differs from results of a previous CPSC led study explained in the Proposed Rule (CPSC, 2020) document which states that all bumpers < 0.8 in (2 cm) tested by the CPSC passed the firmness test, while all bumpers > 1.2 in (3 cm) tested by the CPSC failed the firmness test. Our results are more mixed (Figure 9), where 3 of 4 traditional bumpers in the < 0.8 in (2 cm) group failed firmness testing (S03, S15, and S17), and 1 of 5 passed in the > 1.2 in (3 cm) group (S20; the firm foam product). This could be attributed to the difference in product selection, as we did not test the same products as the CPSC staff. However, because of this difference, we believe it is important to test all bumpers for firmness, regardless of thickness. It is also likely that both

thickness and firmness may play a role in the potential for entrapment or wedging incidents, though we did not directly test such scenarios. While both firmness and thickness may play a role in these situations, other aspects such as the tension in the products due to installation, the fit of the bumper/crib interface, and the fit of the crib mattress within the crib are likely to contribute to the potential for entrapment or wedging (and the ease of getting out of such scenarios).

The CPSC proposed rule suggests that only bumpers at least 1.5 cm must undergo the firmness test, yet our results suggest that in unattached bumpers, a combination of firmness and conformity of some thin products result in failures which may be indicative of a product conformity issue that could present a suffocation hazard. Therefore, we recommend all bumpers undergo firmness testing, regardless of thickness.

While the pass/fail trends were similar across both the test methods, we observed the slatted crib testing with the bumpers secured was slightly less conservative than the flat surface testing with the bumpers unsecured, resulting in fewer failures compared to the flat surface testing with the bumpers unsecured. In the cases of a few products (S02, S07, and S15 in particular), the flat surface testing resulted in more failures compared to the slatted crib testing. When comparing results from testing of long bumper sections in locations 1, 2, and 3 from the flat surface unsecured testing (Table 5) with analogous locations of L1, L2, and L3 from the crib slat secured testing (Table 6), the flat surface unsecured testing resulted in 26 failures while the crib slat secured testing resulted in only 19. We speculate that the unsecured bumper during the flat surface tests represented a "worst case" scenario of a loosely attached or unattached bumper and resulted in more failures. Conversely, the bumpers were securely attached to the crib during the slatted crib testing. Thus, the flat surface testing with the bumpers unsecured offers a different scenario in which the crib bumper is either loosely attached or unattached in the crib environment, resulting in less firmness since it is unstretched and unattached to the crib.

We also note observational differences in the solid surface vs. slatted crib side testing using the standard firmness fixture. The variable of tightness of attachments which depended upon slat locations relative to crib attachment locations on the bumper, personal interpretation of bumper installation instructions, and selection of tightness of attachment mechanism, were all non-existent confounder in the solid surface testing with the bumper unsecured. We propose that because of the more conservative nature of the flat surface testing coupled with the decreased number of confounding variables associated with attaching a bumper to a crib, that flat surface testing with the bumper not attached to anything may offer reliable results representative of a worst-case scenario.

The modified firmness tests using the smaller fixture generally resulted in fewer failures than either method using the larger firmness fixture when common locations were considered. However, when locations of interest (Table 9) were targeted with the smaller fixture, some products failed often (including

S06 which passed all testing with the standard-sized firmness fixture). While the pass/fail trends were generally the same between both the larger and the smaller firmness fixtures, some results surprised us because we hypothesized that the deformation between the crib slats would result in *more* fails using the smaller firmness fixture. One limitation of the smaller firmness fixture is stability, which was less of a concern using the larger firmness fixture with manual adjustments. Particularly on nonuniform bumpers or bumper-like products (braided bumper and loungers), the smaller firmness fixture would not balance well enough to take a reliable reading. Similarly, on S06 which featured a double-layer hook-and-loop attachment, the stability of the fixture on the product was variable.

The modified firmness testing using the smaller fixture on locations of interest elucidated an important feature of mesh bumpers, in that the hook and loop attachment mechanisms result in a different mechanical scenario when installed on a crib compared to the mesh portion alone or compared to the product lying completely flat with only a single layer used for testing. We found similar results in airflow testing in Section 4 below, indicating that the mesh bumpers in particular should be tested in the worst-case scenario location, which, once installed, is often on or near the hook-and-loop attachment location. For this reason, if products installed on a crib feature multiple layers in some locations (such as the hook-and-loop attachments), that the products be tested with the maximum number of layers that could be in contact with an infant's face in a crib.

# 3.5 Firmness Testing Recommendations

We appreciate the simplicity of the recommended test method using the larger disk with a feeler arm tested on a solid surface in specified locations with or without the attachments secured to mimic installation, but we suggest that if a simple pass/fail test is adopted, that the method could be clarified even further and provide more conservative results with testing required on a flat surface with the bumper unsecured. A flat surface is likely more conservative because it is representative of a loosely installed crib bumper on a flat panel crib or underneath a baby's face, not accounting for tension gained from installation. This likely represents a worst-case scenario, which is usually the best scenario in which to test products for safety. We also recommend that bumpers which feature multiple layers when installed (such as the mesh with the hook-and-loop attachment) are tested in those critical configurations. We hypothesize that repeatability of the flat surface unsecured testing is better than the slatted crib secured testing due to a decrease in confounding variables related to installing a bumper onto a crib side.

In the future, we could consider a "pre-tensioning" of the bumper to allow it to be stretched at a predetermined tension for a pre-determined amount of time to mimic initial installation in a crib. If this pretensioning were conducted, it is possible that some of the deformations due to product packaging would be straightened out prior to flat surface unsecured testing. This methodology may represent a realistic scenario where a crib bumper has first been installed on a crib and has then loosened over time. We are unable to speculate on how or if this addition would modify the results of our current study, but it is possible that the deformation present in product S07 may be straightened out with a pre-tensioning protocol. While we cannot recommend a specific product redesign for S07 that would result in passing the firmness test, it is possible that a simple packaging change that does not require the product to fold during packaging would mitigate the failure.

Firmness testing in the traditional method of a disk with a feeler arm is difficult for products that are not flat – i.e., braided bumpers and loungers. We required manual manipulation of the firmness testing device when testing these products, and it is likely that the firmness testing device could be manipulated in a way to pass the testing even if the product is not sufficiently firm. Therefore, we recommend that alternative methods could be explored for products that are not flat. A vertically guided fixture that does not depend upon balancing on a non-flat product is one idea that we have explored in section 7.

If the firmness test method was implemented with our recommendations, the following products we tested would pass: traditional bumpers S04 and S20; mesh bumper S06; vertical bumpers S09 and S10.

# 4. Airflow Testing

#### 4.1 Airflow Overview

Airflow is considered an important parameter when considering a suffocation scenario involving infant soft goods. Based on our review of the in-depth investigations related to crib bumpers and the testimony from January 2020 stating that no suffocation events have occurred with mesh bumpers, we believe an airflow standard that differentiates between a mesh liner without any filling and a traditional crib bumper would mitigate the suffocation hazard related to lack of airflow which likely contributes to suffocation deaths related to crib bumpers. We measured the airflow of the 20 products using four test methods: ASTM D737:2004, BS/EN/ISO 9237:1995, a modified version of the BS 4578:1970 airflow test using a perforated support (the method proposed by the CPSC), and a modified version of the BS 4578:1970 airflow test using an unperforated support.

- The ASTM D737:2004 Air Permeability of Textile Fabrics test involves adjusting the rate of air flow passing perpendicularly through a known circular area (5 cm² for this testing) of fabric to obtain a prescribed air pressure differential (250 Pa) across the top and bottom of the test specimen. From this rate of air flow and pressure differential, the air permeability of the fabric is determined. This test does not prescribe specific requirements related to infant suffocation.
- The BS/EN/ISO 9237:1995 Textiles Determination of the Permeability of Fabrics to Air test is almost identical to the ASTM D737:2004, with the major difference being the prescribed air pressure differential is 10 mm head of water (98 Pa). This test does not prescribe specific requirements related to infant suffocation.
- The BS 4578:1970 airflow test method draws air under negative pressure from the top of a pillow's surface, with the performance requirement stipulating that the pressure differential shall not exceed a certain value while the air flow is maintained at 12 L/min. In its proposed rule for crib bumpers/liners, CPSC staff proposes an airflow requirement using the BS 4578:1970 airflow test method, with modifications that include using a flow rate of 2 L/min airflow, believed to be physiologically representative of a sleeping 3-month-old infant (U.S. EPA, 2009). Based on the results of our own independent literature review, this airflow rate is an appropriate approximation of both (1) minute ventilation, or the amount of bulk gas moved into and out of the lungs in a minute, and (2) instantaneous peak flow rate during each breath, both of which are ~2 to 3 L/min. CPSC staff recommends a modification to the test surface, or support, to include perforations, but we hypothesize that a solid surface may be more conservative (i.e. a worst-case scenario) and representative of a scenario of a crib bumper on a solid panel crib side or a loose bumper underneath an infant's face. We therefore tested samples with both a perforated and an unperforated surface.

#### 4.2 Airflow Methods

#### 4.2.1 ASTM D737:2004 and BS/EN/ISO 9237:1995

We used the TF164B Air Permeability Tester (TESTEX Instrument Ltd., Guangdong, China) to obtain permeability measurements of 16 products (12 Traditional, 2 Mesh, and 2 Vertical crib bumpers) according to the <u>ASTM D737:2004</u> and <u>BS/EN/ISO 9237:1995</u> standards. The 4 products not tested included S08, S11, S12, and S20, all of which had a product thickness larger than what the TF164B could accommodate. Additionally, we tested 5 reference materials that are likely to be present in infant sleeping environments (Table 10).

Sample ID	Material	Thickness (cm)
Α	Faux Lambskin (58% Acrylic, 42% Polyester)	2.11
В	Blanket (Micro mink/100% Polyester Sherpa)	1.38
Foam 1	Polyurethane foam	2.49
Foam 2	Polyurethane/Polyethylene foam	2.43
Foam 3	Polyurethane foam (ultra-conformable: memory foam)	2 54

**Table 10**: Material properties and characteristics of tested reference materials.

For ASTM D737:2004, a 5 cm<sup>2</sup> test head and 250 Pa pressure differential was used. For the BS/EN/ISO 9237:1995, a 5 cm<sup>2</sup> test head and 98 Pa pressure differential was used. The general procedure for testing products using the TF164B included placing the specimen over the air inlet, placing the specimen ring over the specimen to stretch it out over the air inlet, and then running the test on the machine which clamps the pneumatic sample holder onto the specimen (Figure 10).



**Figure 10**: Testing setup for ASTM D737:2004 and BS/EN/ISO 9237:1995 using the TF164B (left) and 5 cm2 test head (right).

In general, the testing area for all samples were aligned with the centerline of the sample's width (i.e. height as it would be used on a crib). Some samples, however, had unique features and characteristics that necessitated testing at more than one location (Figure 11). For example, S01 had quilting that we believed would affect permeability value, while S06 and S07 had multiple hook and loop fastener layers in some locations due to the attachment mechanisms when installed according to the instructions on a crib. Using the methods specified, we assessed the airflow of the 16 samples and their representative testing locations described under the ASTM D737:2004 and BS/EN/ISO 9237:1995 standard testing.





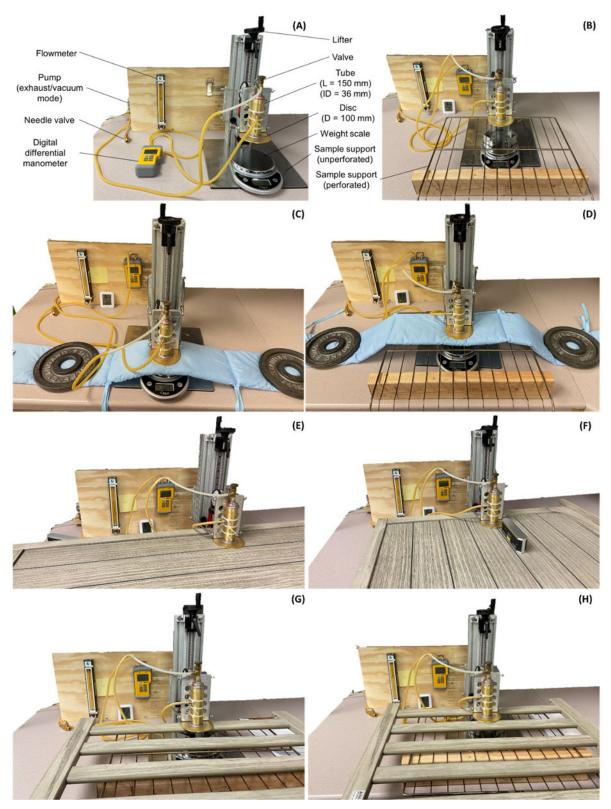


**Figure 11**: Unique features affecting airflow testing location
From left: S01 (quilting), S07 (hook-and-loop – four layers due to two overlayed hook-and-loop attachments), S06 (hook-and-loop – double layer).

#### 4.2.2 Modified BS 4578:1970 for 2 L/min

The testing schematic and experimental setup for the modified BS 4578:1970 airflow test are demonstrated in Figure 12. The experimental apparatus included a metal tube (length: 150 mm, internal diameter: 36 mm), on the bottom of which a metal flange (outer diameter: 100 mm) was attached. A vertical lifter mechanism (Leshner & Associates, Inc., Elkton, MD) lowered the tube-flange assembly such that the testing sample experienced a thrust of 10 N (verified by reading the weight scale). The top of the tube was connected to the inlet of a flowmeter (E500; Matheson Tri-Gas, Inc., Irving, TX), the outlet of which was connected to the vacuum/suction side of an AC linear piston vacuum pump (VP0125; Nitto Kohki USA, Inc., Roselle, IL). A needle valve attached to the pump allowed for gross control of the airflow, while a diaphragm-type valve within the flowmeter allowed for fine adjustment of the airflow. From the side of the metal tube, a connection was taken to a digital differential manometer (EM201B; UEi Test Instruments, Portland, OR; accuracy 0.03 in H<sub>2</sub>O and resolution 0.001 in H<sub>2</sub>O for our measured ranges). The pressure differential indicated by the manometer was noted when the flow rate was adjusted to 2 L/min. The testing was performed with each product lying on both a rigid perforated support and on a rigid unperforated surface. In the case of a single product (S19), we observed non-uniform filling of the traditional-style bumper. For example, the middle of the product featured sparsely packed batting, while

the edges of the product near the seams featured more densely packed and doubled-over batting. This particular product was marketed as "handmade", and thus did not likely undergo rigorous manufacturing and quality control compared to other products. For this reason, we chose to test the product in multiple locations of interest in order to capture the potential worst-case-scenario.

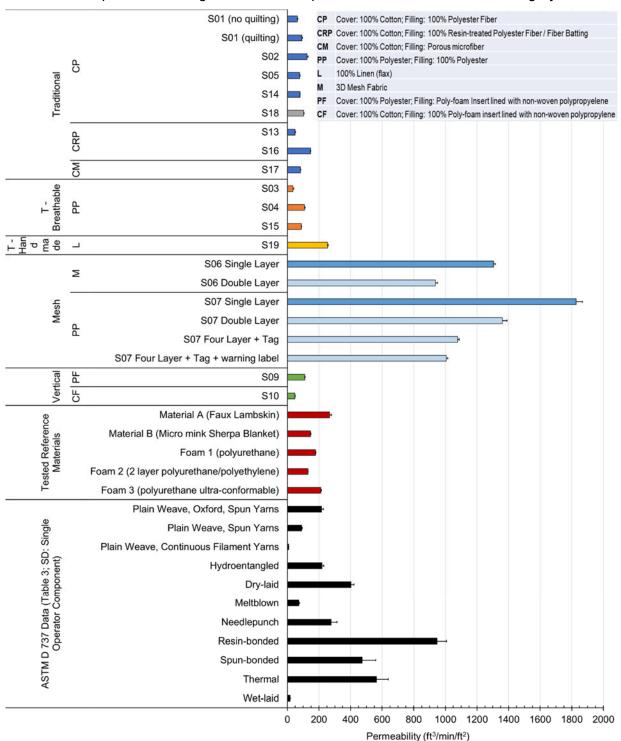


**Figure 12**: Modified BS 4578:1970 experimental setup for unperforated (A) and perforated (B) support, and testing photographs of permeability testing using the unperforated (C) and perforated (D) support, solid crib side (E), solid crib side on a groove (F), on slat (G), and between slats (H). The weights in (C) and (D) were used to hold the bumper in place and were situated as to not stretch the bumper.

#### 4.3 Airflow Results

#### 4.3.1 ASTM D737:2004

The results are presented in Figure 13, with the products classified based on category and material.

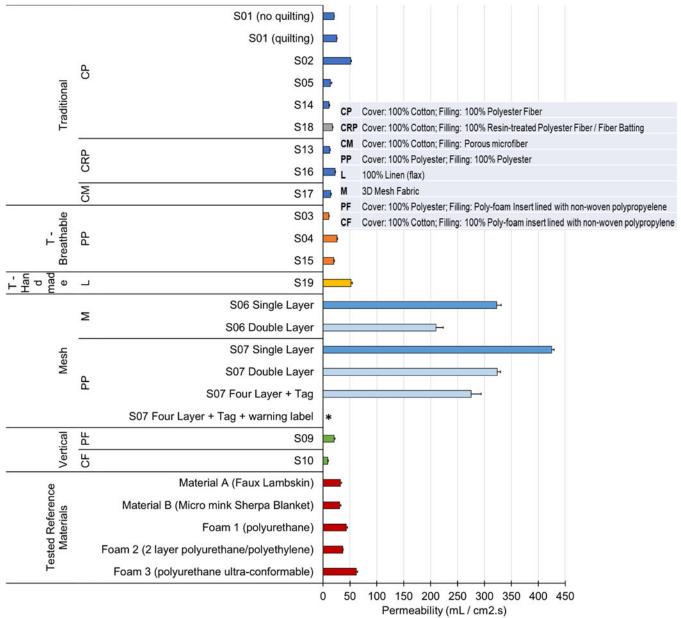


**Figure 13**: ASTM D737:2004 Permeability results of tested samples, reference materials, and normative data from the standard.

To assess the relationship between product thickness and product permeability, we conducted a correlation analysis on the traditional crib bumpers. Due to a violation of normality for the permeability data (Shapiro-Wilk p<0.05), we ran the non-parametric Spearman's Rank Order correlation on SPSS (IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp). We found a weak negative relationship between product thickness and product permeability,  $\rho_{(10)} = -.022$ , p = 0.945.

#### 4.3.2 BS/EN/ISO 9237:1995





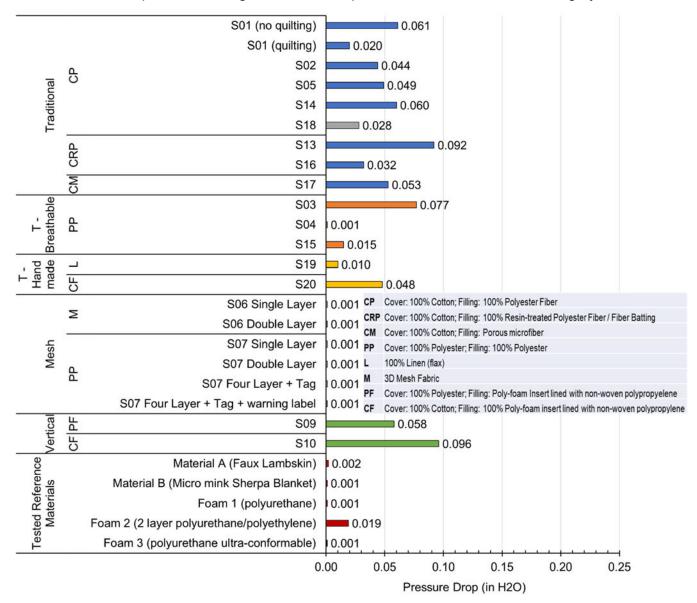
**Figure 14**: BS/EN/ISO 9237:1995 permeability results of tested samples and reference materials. \*The S07 hook and loop fold + tag + warning label testing was not possible due to prior cross sectioning of the sample at that location.

To assess the relationship between product thickness and product permeability, we conducted a correlation analysis on the traditional crib bumpers. Due to a violation of normality for the permeability data (Shapiro-Wilk p<0.05), we ran the non-parametric Spearman's Rank Order correlation on SPSS

(IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp). We found a small negative relationship between product thickness and product permeability,  $\rho_{(10)} = -.132$ , p = 0.683.

## 4.3.3 Modified BS 4578:1970 for 2L/min (perforated support)

The results are presented in Figure 15, with the products classified based on category and material.



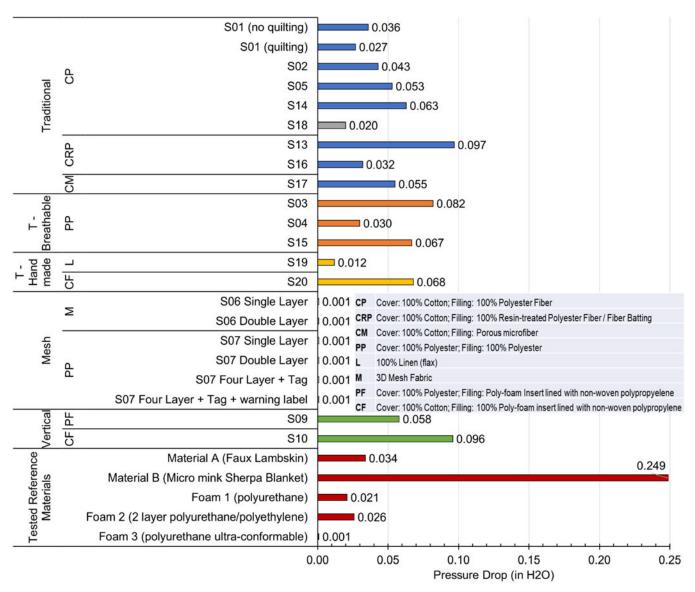
**Figure 15**: BS 4578:1970 permeability (pressure drop) results of tested samples and reference materials for the perforated support.

To assess the relationship between product thickness and permeability (pressure drop) for the perforated support, we conducted a parametric Pearson's correlation analysis on the traditional crib bumpers using SPSS (IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp). We found a weak positive relationship between product thickness and product permeability (pressure drop) for the perforated support,  $r_{(13)} = .157$ , p = 0.608.

The relationship between the ASTM D737:2004 permeability measurements and the modified BS 4578:1970 permeability (pressure drop) measurements for the perforated support were assessed using Pearson's correlation and linear regression analysis on the traditional crib bumpers using SPSS (IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp). To ensure appropriate comparison, only the samples measured using the ASTM D737:2004 standard were compared with the corresponding sample measurements of the modified BS 4578:1970. We found a strong negative relationship between the ASTM D737:2004 permeability (cfm) and the modified BS 4578:1970 permeability (pressure drop in H<sub>2</sub>O) for the perforated support,  $r_{(13)} = -.450$ , p = 0.123. A linear regression established that ASTM D737:2004 permeability (cfm) could not predict modified BS 4578:1970 permeability (pressure drop in H<sub>2</sub>O), F(1,11) = 2.789, p = 0.123,  $R^2 = 0.202$ .

## 4.3.4 Modified BS 4578:1970 for 2L/min (unperforated support)

The results are presented in Figure 16, with the products classified based on category and material.



**Figure 16**: BS 4578:1970 permeability (pressure drop) results of tested samples and reference materials for the unperforated support

To assess the relationship between product thickness and permeability (pressure drop) for the unperforated support, we conducted a parametric Pearson's correlation analysis on the traditional crib bumpers using SPSS (IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp). We found a weak negative relationship between product thickness and product permeability (pressure drop),  $r_{(13)} = -.181$ , p = 0.553.

The relationship between the ASTM D737:2004 permeability measurements and the modified BS 4578:1970 permeability (pressure drop) measurements for the unperforated support were assessed using Pearson's correlation and linear regression analysis on the traditional crib bumpers using SPSS (IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp). To ensure appropriate comparison, only the samples measured using the ASTM D737:2004 standard were compared with the corresponding sample measurements of the modified BS 4578:1970. We found a strong negative relationship between the ASTM D737:2004 permeability (cfm) and the modified BS 4578:1970 permeability (pressure drop in  $H_2O$ ) for the unperforated support,  $r_{(13)} = -.701$ , p = 0.008. A linear regression established that ASTM D737:2004 permeability (cfm) could predict modified BS 4578:1970 permeability (pressure drop in  $H_2O$ ) for the unperforated support, F(1,11) = 10.605, p = 0.008,  $R^2 = 0.491$ . The regression equation can be expressed as:

Predicted ASTM D737:2004 permeability = 173.1 – 1532.13 (modified BS 4578:1970 permeability, unperforated).

## 4.3.5 Modified BS 4578:1970 - Solid Crib Side, Crib Slat, and Between Slats

For the purpose of comparison, we tested the pressure drop on solid crib panel in two locations (*not* on a groove and on a groove), on a slat, and between slats. Table 11 shows that the testing between slats and the testing on the solid panel with the groove did not result in a pressure drop, indicating there was free airflow. The on slat and solid side panel with no groove testing conditions resulted in measurable pressure drops, notably higher than most crib bumper products. Solid sides or slats are not permeable, and using this test method featuring a flat probe, the probe was able to form a seal on the flat solid surface. In a real-life scenario, the infant nose and mouth feature three-dimensional geometry that likely prevents a seal from forming on solid rigid surfaces like a solid side or slat. However, this test does show the importance of an air channel (illustrated by the small groove on the solid panel) in airflow testing. For this reason, a probe more representative of an infant's nose geometry could be explored in the future. We hypothesize that a probe with nose-like geometry and/or biofidelic stiffness would result in no pressure drop during airflow testing on these solid surfaces, due to presence of air channels and the lack of seal formation.

**Table 11**: Permeability (pressure drop) for the solid crib side and crib slat.

Condition		Pressure Drop (in H <sub>2</sub> O)
Solid Side	No Groove	0.435
	Groove	0
Slat	On Slat	0.067
	Between Slats	0

## 4.3.6 Statistical Analyses and Test Method Comparisons

For the ASTM D737:2004 and the BS/EN/ISO 9237:1995 standards, the differences in permeability between traditional and mesh bumpers were assessed using two-tailed independent samples t-tests. Mesh bumpers demonstrated higher permeability values compared to traditional bumpers for both the ASTM D737:2004 (1252.4  $\pm$  327.2 cfm vs. 101.1  $\pm$  57.0 cfm: Mean  $\pm$  SD;  $t_{16}$  = -12.2, p = 0.002) and the BS/EN/ISO 9237:1995 (311.1  $\pm$  78.6 mL/cm<sup>2</sup>.s vs. 22.7  $\pm$  14.3 mL/cm<sup>2</sup>.s: Mean  $\pm$  SD;  $t_{15}$  = -12.8, p <0.001). The mesh bumpers allowed 12 to 14 times the rate of airflow compared to traditional bumpers, making either of these tests suitable to differentiate between mesh and traditional bumpers.

For the BS 4578:1970 standard, the differences in the pressure drop (inches of  $H_2O$ ) between traditional and mesh bumpers can be described using descriptive statistics (as opposed to comparative statistics) since mesh bumpers indicated pressure drops below the measurable limit (<0.0009 in  $H_2O$ ). On average, the traditional bumpers indicated a pressure drop of 0.0482  $\pm$  0.0259 in  $H_2O$  for the unperforated support and 0.0431 $\pm$  0.0274 in  $H_2O$  for the perforated support. We found a weak positive relationship between the modified BS 4578:1970 permeability (pressure drop in  $H_2O$ ) values for the unperforated support compared to the perforated support,  $r_{(13)} = 0.102$ , p = 0.741. A linear regression established that BS 4578:1970 permeability (pressure drop in  $H_2O$ ) for the unperforated support could not predict the permeability (pressure drop in  $H_2O$ ) to the perforated support to statistical significance, F(1,11) = 0.115, p = 0.741,  $R^2 = 0.010$ . The regression equation can be expressed as:

Predicted modified BS 4578:1970 permeability, unperforated = 0.042 + 0.097 \* (modified BS 4578:1970 permeability, perforated).

### 4.4 Airflow Discussion

All four of the airflow tests we used differentiated between the mesh liners and the traditional bumpers. It is to be noted that some samples (S08, S11, S12, and S20) could not be tested using the ASTM D737:2004 since they had a product thickness larger than what the test fixture could accommodate, while the Modified BS 4578:1970 was able to accommodate all samples regardless of thickness. Within the traditional bumper product class, we observationally grouped bumpers with the same material compositions of the cover and filling, with no obvious trends related to each of those subcategories. Product S19, which is a handmade artisanal product made of flax linen, likely did not undergo the same manufacturing rigor as the other commercially made bumpers. We observed that the filling material in this bumper was not densely packed and appeared non-uniform throughout the product, so we tested it in multiple locations of interest representing the thinnest and thickest portions of the

product. We also noted an influence of the warning labels and tags sometimes decreasing airflow in the mesh products in particular. Any airflow standard should require products be tested in the "worst-case" scenarios or in locations of interest. In the case of the mesh products, the worst-case scenarios in relation to airflow are locations where multiple layers of the product interact at an attachment on a crib slat, and/or where tags and labels are present on the bumper surface.

Our team attempted to compare the airflow from the modified BS 4578:1970 standard to a modeled infant airway. However, due to the lack of experimental data and vast number of assumptions required for using common airflow equations, we were unable to contextualize the values found experimentally with physiological comparisons. Future research could be done to both obtain experimental data and also to build a mathematical model of infant breathing to better understand the impact of internal plus external factors contributing to airway resistance during breathing.

CPSC staff has previously recommended using the modified BS 4578:1970 airflow test (2 L/min) with a maximum suggested threshold limit of 0.003 in H<sub>2</sub>O (CPSC, 2019). CPSC staff used a perforated platform while we tested both perforated and solid (unperforated) platforms. We note that when CPSC staff tested bumpers and liners using an unperforated platform, the pressure drop rose significantly for the mesh bumpers. We did not see the same phenomenon during our testing; however, we performed our testing at a 2 L/min flow rate, whereas CPSC staff performed their unperforated-platform testing at the BS 4578:1970 standard's original, higher flow rate of 12 L/min. Our results are more intuitive, meaning that we would expect airflow to not be impacted as much by a mesh product without any filling, and the difference between the flow rates likely resulted in the difference in results. Our measurements are generally higher compared to the CPSC's testing (average 0.048 in H<sub>2</sub>O unperforated; 0.044 in H<sub>2</sub>O vs. 0.0139 in H<sub>2</sub>O perforated), but the threshold value of 0.003 in H<sub>2</sub>O suggested by CPSC staff would differentiate between all mesh liners without filling and traditional bumpers during unperforated testing. Based on our results, a 0.003 in H<sub>2</sub>O maximum pressure threshold is sufficient to differentiate between mesh liners without filling and traditional bumpers, when tested on an unperforated platform.

We recognize that a threshold of 0.003 inches of water would require a measuring instrument with a very low resolution, likely near 0.0005 in  $H_2O$ . Furthermore, the instrument we used stated an accuracy of 0.03 in  $H_2O$  and a resolution of 0.001 in  $H_2O$ , so our results should be considered within the context of the limitations of our measurement device. An instrument of increased precision would be costly, so in the future, we could develop a probe which features a *smaller area*. Not only would this raise the pressure values to allow for a higher and more reasonable measurable threshold, but a smaller area would also come closer to a physiological scenario more representative of the area of infant nares.

The modified BS 4578:1970 testing on the solid crib side and crib slat with no crib bumper samples indicated that the solid crib side surface may pose a higher impediment to airflow than the slat (pressure drop: 0.435 in H<sub>2</sub>O vs. 0.067 in H<sub>2</sub>O), while grooves on the solid crib panel and testing between slats may pose very low impediment to airflow (0 in H<sub>2</sub>O). This supports many of our recommendations throughout this document indicating **the solid panel represents the worst-case breathing scenario in crib bumper testing**. It also shows the potential importance of grooves in solid panels, which could be further explored. It is worth noting that while the solid panel and slats resulted in comparatively high pressure drops, that these results are likely due to the seal resulting from the flat probe pressed flush against the flat surfaces. In a physiological scenario, the three-dimensional geometry of the nose and mouth would likely mitigate a perfect seal on the flat rigid surface, so the pressure drop on the flat surfaces would likely be zero. The introduction, then, of a crib bumper or bumper-like product which *can* conform to the face and potentially form a seal around the nose and mouth when pressed against a solid surface, presents the suffocation scenario. So, while testing crib scenarios without any products installed is helpful, it is not useful to compare the results to the crib bumper and bumper-like product results when considering a real-life scenario.

The characteristic common between the products that passed airflow testing was the mesh design. Both S06 and S07 featured mesh with *no internal filling*. Even when multiple layers of the mesh products were tested, the permeability of these products far exceeded most other products. However, multiple layers *did* impact the permeability results, most easily seen in the decreasing bars for S06 and S07 during permeability testing in Figures 13 and 14. It is important that when conducting testing airflow, the worst-case scenarios (multiple layers) are tested.

We found no discernable relationship between firmness and airflow. Thickness was not strongly related to airflow in the samples we tested using any method. Variability and repeatability of various test methods were not assessed during this testing. We hypothesize that using an unperforated (solid) surface would lead to less variability of results, though this could be explored further. Due to the challenges associated with reading the low values of pressure drop (in  $H_2O$ ), we utilized a digital manometer instead of an inclined manometer (as recommended in BS 4578:1970) in the interest of a higher measurement resolution, and if this test became part of a standard, a tolerance of 0.001  $\pm$  0.0005 in  $H_2O$  could be specified, though this value may not be practical due to instrument limitations. Finally, there are additional limitations in setting a threshold limit so near the lowest discernible measurement value of any testing device. For this reason, the area of the test device could be decreased, which would increase the pressure drop for all products and may come closer to representing a physiological scenario.

### 4.5 Airflow Recommendations

Each method we tested resulted in differentiation between mesh and traditional bumpers. If the primary goal of airflow testing is to differentiate between mesh and traditional bumpers, any of these four airflow tests will suffice. We agree with the CPSC staff that a modified version of BS 4578:1970 is more similar to a realistic infant breathing scenario compared with other permeability testing. Therefore, we agree that the modified airflow test BS 4578:1970 with a 2 L/min flow rate on an unperforated support (representative of a solid panel or crib slat) with a 0.003 in H<sub>2</sub>O threshold could be adopted as the airflow standard. However, the inherent limitations of establishing such a low threshold relative to the manometer's resolution is concerning, so we could further explore smaller probe areas which would likely increase all pressure values. We suggest using an unperforated support, as results from our study using the unperforated support were able to differentiate between all mesh liners and traditional crib bumpers we tested. Thus, the unperforated support may result in a more repeatable and a more conservative test.

If the airflow test method was implemented with our recommendations, the following products we tested would pass: mesh bumpers S06 and S07. Note that the braided bumper (S08) and the lounger products (S11 and S12) were unable to be tested using this method. The curved nature of the braided bumper and lounger products did not allow the flat testing probe featuring a diameter much larger than an infant's nose to make full contact with the surfaces, such that portions of the probe were never covered by the product during testing. A smaller probe area may remedy this scenario, allowing measurement of curved surfaces.

Product S19 (the "handmade" traditional bumper) presented challenges during airflow testing due to the non-uniform filling. We recommend that if products feature varied thicknesses or different material compositions that could be in direct contact with an infant, that multiple locations of interest are tested using the airflow testing method. This helps assure that the worst-case scenario would be captured in the data collection.

When taken with the firmness testing from Section 3, **S06** is the only product that would currently pass both the recommended firmness and airflow tests. However, it is likely that minor redesigns of some products may allow them to also pass both tests. As mentioned in Section 3, S07 failed the firmness test due to the fold in the product which was apparent even after laundering. While we cannot recommend a specific product redesign that would result in passing that test, it is possible that a simple packaging change that does not require the product to fold would mitigate the failure. We also note our recommendation for both firmness and airflow tests as a requirement for all products. Although a bare crib slat or solid panel side has no airflow according to the test performed, the firmness of the bare surface is what makes the scenario safe, regardless of the lack of airflow. In a real-life scenario, the three-

dimensional geometry of the infant's nose and mouth would likely prevent a seal from forming on a flat rigid surface. The firmness testing method we recommend does *not* test for firmness <u>equivalent</u> to a crib slat or solid panel side, and instead allows for some deformation. Therefore, we cannot consider even a firm product (defined by passing the firmness test) to be equivalent to a bare crib slat or solid panel side, and thus we recommend that *both* firmness and airflow must be tested for all crib bumper and bumper-like products. The CO<sub>2</sub> rebreathing testing conducted in Section 5 supports this same idea by showing that even products which are sufficiently firm to pass the firmness test still exhibit increased levels of CO<sub>2</sub> rebreathing compared to the bare crib slat or side panel. Therefore, **we recommend that all products undergo both firmness and airflow testing.** 

We also note that climb-out risk (Section 6) is not considered in the assessment above, and that S06 and S07 perform *worse* than most other products in climb-out testing, though no pass/fail threshold for climb-out testing has yet been established.

# 5. CO<sub>2</sub> Rebreathing Testing

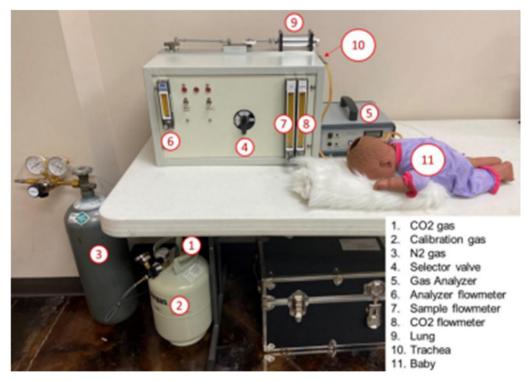
# 5.1 CO<sub>2</sub> Rebreathing Overview

The literature review we conducted suggested that CO<sub>2</sub> rebreathing is an important characteristic to understand when considering infant suffocation risk. Airflow and rebreathing, while related, are not the same. Some airflow tests evaluate air flowing into one side of a product and out of the other, which is not necessarily the scenario when considering a crib bumper. Instead, an infant expires air into a bumper, then inspires air from or through the bumper. So, rather than an evaluation of the air flowing only *through* a material, a more accurate scenario may be airflow (and the gas composition of that air) into and out of the same side of the bumper product. While the modified British Standard (BS 4578:1970) evaluates the pressure required to inspire through a product at a breathing flow rate representative of an infant, it does not address the issue of the composition of gas that the infant may actually be inspiring. For this reason, we proposed and tested all 20 products using a CO<sub>2</sub> rebreathing test machine. While we understand that this complex rebreathing test method is not suitable for a standard, we hope to interpret the results of this robust testing in relation to the more simplified airflow and firmness tests to give us a better understanding of how these various tests are related or not, guiding future standard development.

# 5.2 CO<sub>2</sub> Rebreathing Methods

We used a mechanical breathing model to measure CO<sub>2</sub> rebreathing in an infant surrogate. This CO<sub>2</sub> rebreathing model is an iteration of the setup described by Maltese and Leshner (Maltese & Leshner, 2019) (Figure 17). The model consists of 12 mechanical parts to simulate respiratory volume and frequency typical of an infant. CO<sub>2</sub> is introduced into the lung to simulate the infant's rate of metabolism. A mechanical "lung" of 120 ml volume was applied to simulate natural breathing at a frequency of 45 per minute and volume cycling between 65 and 100 ml. A pump was also used to draw a small sample at 75 ml/min. Interaction between the manikin's face (

analyzer (Model 906; Quantek Instruments, MA). The manikin head was weighted with lead shot and epoxy to simulate an infant's head weight (0.66 kg), and metal piping was connected to the manikin nares to serve as the nasal airway for the simulated inspiration and expiration.



**Figure 17**: Current CO<sub>2</sub> rebreathing testing setup.

We collected rebreathing data on 20 infant products and 3 reference materials in a variety of scenarios. Each CO<sub>2</sub> measurement was repeated 3 times for most conditions to ensure repeatability. Before and after each test, the system was allowed to stabilize for five minutes, and CO<sub>2</sub> readings were collected with the infant surrogate's nares unobstructed. Humidity and temperature were recorded before and after each test session.

We installed 18 (S01-S10, S13-S20) of the products on a crib with slats, and 14 (S01-S06, S08, S13-S14, S16-S20) of the products on a solid panel crib, and we tested various infant surrogate scenarios. For the solid panel testing, S07 specifically included instructions to not install on a solid panel crib side, S09 and S10 were vertical bumpers and could not be tested on a solid panel, and S15 was designed for a mini crib and was not long enough for the solid panel installation. Lounger products S11 and S12 were tested differently as described in the following paragraph. For the slatted crib, the scenarios were based on the position of the surrogate's nares and included: on a slat (on slat), between slats (between slat), in the intersection of the product and mattress on a slat (slat corner), and the intersection of the product and mattress closest to the corner of the crib (3-way corner). We also tested the mesh products (S06 and S07) for the on slat, between slat, and slat corner with multiple layers resulting from the hook and loop attachment method. For the solid panel crib, the testing scenarios included: on panel (on panel),

intersection of the panel and mattress (panel corner) (Figure 18). All scenarios were also tested *without* the presence of a bumper product to get baseline rebreathing data.



**Figure 18**: Different rebreathing testing scenarios inside a crib without a bumper in place. Slatted crib: (A) On slat. (B) Between slats. (C) Slat corner. (D) 3-way corner; Solid panel crib: (E) On panel. (F) Panel corner.

For products S11 and S12 (lounger products), the testing scenarios were modified due to the unique product designs. We tested with the manikin: facedown, facing the side from inside of the product, facing the inside corner, and facing the side from outside of the product. (Figure 19). These four positions were tested both on a hard surface and on a crib mattress in a slatted crib. The intersection between product and crib mattress was also tested when the product was on a crib mattress in a slatted crib.











**Figure 19**: Rebreathing testing scenarios for lounger products. (A) Facedown. (B) Facing the side from inside. (C) Inside corner. (D) Facing the side from outside. (E) Intersection between sample and mattress.

Five products and 3 reference materials (S01, S07, S13, S16, S20, Material A (faux lambskin), Material B (micro-mink / 100% polyester blanket), and Material C (lambskin)) were also tested while covering the face of the supine-lying surrogate in order to understand the impact of accidental face covering of a loose crib bumper or soft goods. Lastly, measurements were taken with the manikin facedown into only the crib mattress with fitted sheet while the manikin was oriented both along the length (longitudinal) and the width (perpendicular) of the crib.

Reference materials A, B, and C were tested with the manikin in a facedown scenario, both on a hard surface and on a crib mattress in order to give context of the results of the crib bumper data to known hazardous materials.

It is important to note that the *numerical values* resulting from this test method are not the ultimate outcome. Rather, the *comparison* between known safe scenarios (i.e., unobstructed side lying on a crib mattress) and known unsafe scenarios (i.e., face down on lambskin) is more informative in interpreting the results.

## 5.3 CO<sub>2</sub> Rebreathing Results

Raw data from all test methods is provided in Appendix C. Below, we discuss the most important findings. The unobstructed side-lying baseline value averaged 4.0% rebreathed CO<sub>2</sub> between all tests. This gives us a baseline by which to contextualize the rest of the results. Physiologically, unobstructed breathing results in < 1% rebreathed CO<sub>2</sub>. Therefore, we interpret the results from our testing based on the *increase* from this 4.0% baseline value. For example, if a product in a test scenario gives a 6.8% rebreathed CO<sub>2</sub> reading, we can interpret that as an increase of 2.8%.

#### Rebreathing Without a Bumper

CO<sub>2</sub> rebreathing data for the various scenarios *without* a bumper in place are: On Slat (4.6%), Between Slats (3.8%), Slat Corner (4.0 %), 3-way Corner (3.9 %), Solid Panel (4.8 %), and Solid Panel Corner (4.6 %).

#### Overall ANOVA: CO<sub>2</sub> Rebreathing in All Crib Bumper Scenarios

We conducted a one-way ANOVA to compare the  $CO_2$  rebreathing values (dependent variable) at the 6 locations of testing within the crib with crib bumpers installed (On Slat, Between Slats, Slat Corner, 3-way Corner, On Solid Panel, and Solid Panel Corner; independent variables) using SPSS (IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp).  $CO_2$  rebreathing data are presented as mean  $\pm$  standard deviation by location: On Slat (7.4  $\pm$  1.2%), Between Slats (7.1  $\pm$  1.1%), Slat Corner (6.2  $\pm$  1.1%), 3-way Corner (6.1  $\pm$  1.4%), Solid Panel (7.7  $\pm$  0.9%), and Solid Panel Corner (6.7  $\pm$  1.3%).  $CO_2$  rebreathing (%) was significantly different between test locations, F(5,86) = 4.30, p = 0.002. A Bonferroni post-hoc pairwise comparison (corrected significance p <0.01) indicated that  $CO_2$  rebreathing values were significantly different between the 3-Way Corner and the Solid Panel (p = 0.006).

### On Slat vs. Solid Panel CO2 Rebreathing

Since the On Slat and Solid Panel testing conditions resulted in the highest rebreathed  $CO_2$  values, we considered these cases to be our "worst case" scenarios for  $CO_2$  rebreathing. To assess the difference in  $CO_2$  rebreathing between samples On Slat, compared to on the Solid Panel, we conducted a two-tailed paired samples t-test.  $CO_2$  rebreathing was not significantly different between the products On Slat vs. Solid Panel (Mean  $\pm$  SD:  $7.5 \pm 1.2\%$  vs.  $7.7 \pm 0.9\%$ ;  $t_{13} = -0.838$ , p = 0.417). Since the mean values in the Solid Panel scenario were slightly greater than the On Slat scenario, we utilized the Solid Panel values henceforth to statistically compare thickness vs.  $CO_2$  rebreathing and Modified BS 4578:1970 permeability (unperforated) vs.  $CO_2$  rebreathing.

## Product Thickness vs. CO2 Rebreathing

A Pearson correlation analysis of bumper thickness compared to  $CO_2$  rebreathing over a solid panel using SPSS (IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp) indicated a weak positive relationship between bumper thickness and  $CO_2$  rebreathing,  $r_{(14)}$  = .176, p = 0.547.

### Modified BS 4578:1970 Permeability (Unperforated) vs. CO₂ Rebreathing

A Pearson correlation analysis was conducted on SPSS (IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp) to compare permeability to  $CO_2$  rebreathing over a solid panel. We found a weak negative relationship between permeability and  $CO_2$  rebreathing,  $r_{(13)} = -.355$ , p = 0.234.

## Firmness and Material vs. CO2 Rebreathing

In order to include vertical bumpers in analyses, we must focus now on the On Slat condition since a vertical bumper cannot be attached to a solid panel. Figure 20 shows CO<sub>2</sub> rebreathing measurements for each product in the On Slat scenario. The CO<sub>2</sub> measurements vary from 5% to 10% in all tested products. In particular, there is no discernable difference in the rebreathed CO<sub>2</sub> values in any product category, or between product materials.

## Rebreathing With Bumpers Covering the Face

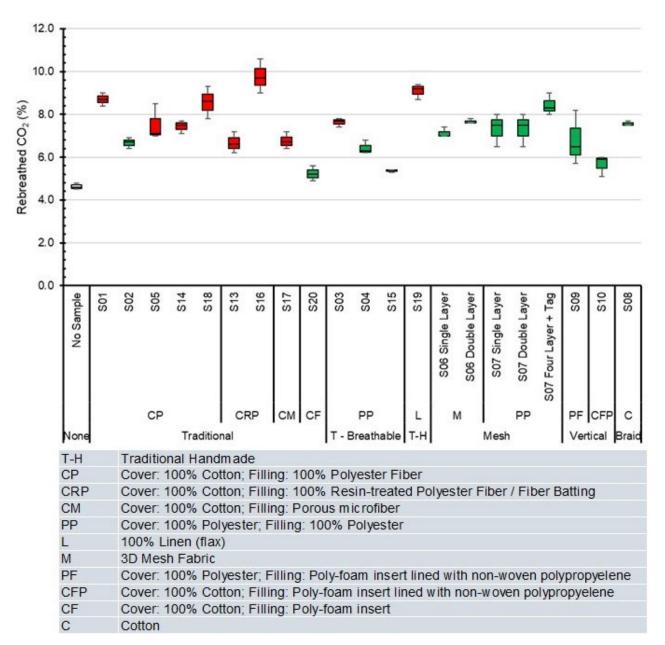
Average values for rebreathed CO<sub>2</sub> for the products (S01, S07, S13, S16, S20, Materials A, B, and C) were: 7.4%, 6.9%, 6.3%, 7.0%, 5.8%, 10.4%, 8.4%, and 8.7%, respectively. A paired-sample t-test of these values with the Between Slats results for the products show no statistical difference (p=0.697).

#### Between Slats CO<sub>2</sub> Rebreathing

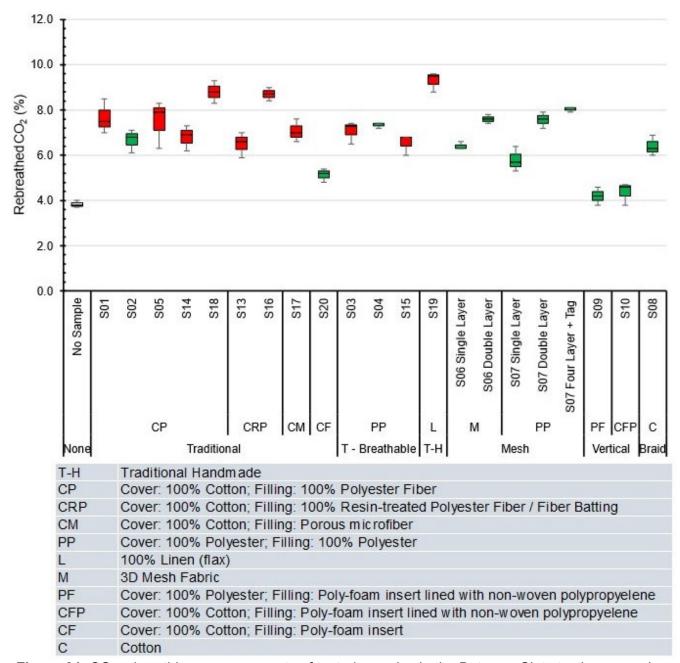
Because no differences were found between product types in our "worst-case" scenarios of On Slat and Solid Panel, we also explored the Between Slats condition in depth (Figure 21). In this condition, the vertical bumper category exhibited results similar to the unobstructed testing, which makes sense considering the products do not bridge the gap between slats. Otherwise, no discernable differences were apparent between product categories.

Between Slats CO<sub>2</sub> Rebreathing vs. Modified BS 4578:1970 Permeability (Perforated) and Product Thickness

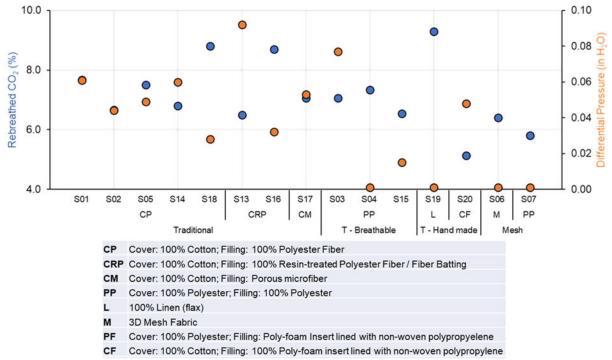
To further assess the nature of between slats CO<sub>2</sub> rebreathing for traditional and mesh bumpers in the context of permeability and product thickness, Pearson correlation analyses were performed using SPSS (IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp) between modified BS 4578:1970 permeability (perforated) compared to between slats  $CO_2$  rebreathing, and product thickness compared to between slats  $CO_2$  rebreathing. We found a weak negative relationship between  $CO_2$  rebreathing and permeability,  $r_{(15)} = -.151$ , p = 0.591, and a weak positive relationship between  $CO_2$  rebreathing and product thickness,  $r_{(13)} = .228$ , p = 0.414. These relationships are similar to the ones presented above for solid panel  $CO_2$  rebreathing. The relationship between the modified BS 4578:1970 permeability (perforated) and between slats  $CO_2$  rebreathing is presented in Figure 22.



**Figure 20**: CO<sub>2</sub> rebreathing measurements of tested samples in the On Slat testing scenario. Box plots colors indicate the samples have passed (green) or failed (red) firmness testing. The "no sample" boxand-whiskers indicates the rebreathed CO<sub>2</sub> (%) for unobstructed nares of the surrogate.



**Figure 21**:  $CO_2$  rebreathing measurements of tested samples in the Between Slats testing scenario. Box plots colors indicate the samples have passed (green) or failed (red) firmness testing. The "no sample" box-and-whiskers indicates the rebreathed  $CO_2$  (%) for unobstructed nares of the manikin.



**Figure 22**: Between Slats rebreathed CO<sub>2</sub> (in blue) and modified BS 4578:1970 permeability (perforated) (in orange) from traditional and mesh crib bumper samples. Note that S01 and S02 data points are overlaid.

# 5.4 CO<sub>2</sub> Rebreathing Discussion

Our findings indicate that rebreathed CO<sub>2</sub> in the Solid Panel or On Slat conditions is weakly related to bumper thickness, moderately related to permeability, and inconclusively related to whether the bumper has passed the firmness test. While it is likely that a combination of these factors contributes to the rebreathed CO<sub>2</sub>, it is also likely that other factors that facilitate the seal between an infant's nares and the bumper play an important role. These factors may include how densely and consistently the filler material is packed into the bumper, how much the bumper deforms due to its attachment mechanism to the crib slats/panel and gravity, and how the bumper can impact (through the coefficient of friction of its outer material) the ability of an infant who has rolled into the bumper, and/or has been entrapped, to roll back (self-correct). These additional factors may contribute to the question that necessitate broader assessment of the rebreathing potential of crib bumpers – will the crib bumper, in its natural state of use, create the means for a pocket of CO<sub>2</sub> to build up within it?

The worst-case scenario of a bumper on a solid surface was clarified with our CO<sub>2</sub> rebreathing testing. Both the On Slat and Solid Panel testing conditions exhibited higher unobstructed values, and higher values with bumper products installed, across all product classes. This provides further justification for using a solid surface for testing in both the airflow performance and firmness testing. While the Between

Slat CO<sub>2</sub> rebreathing testing did differentiate between vertical bumpers and other product categories, it does not represent the "worst-case" scenario of a bumper on a solid surface. The vertical bumper results from the On Slat condition were not different than traditional bumper results (Figure 20). The mesh liners did not perform better than some traditional bumpers in the On Slat condition. When compared with the airflow results from section 4, these results could be puzzling. However, the rebreathing experiment did not include any force application when the mannequin's face was in contact with the installed bumper, thus the ability of the product to form a seal in those tested conditions is not considered in this rebreathing analysis. It is likely that if the rebreathing study were to be repeated with a constant force application on the infant, that the results may be more similar to the airflow testing which accounts for a constant force.

To better contextualize our rebreathing results, we look to the medical literature review we conducted. One human study on infants found that inspired (or rebreathed) CO<sub>2</sub> measured up to 6.4% when the infant was described in a face straight down into a mattress position prior to corrective action taken by the infant to prevent suffocation (Chiodini and Thach, 1993). Our rebreathing method measures ~4.0% as the baseline condition during unobstructed breathing, so the difference between the baseline and each testing scenario could be compared to the results from Chiodini and Thach (1993). For example, during On Slat testing, product S16 exhibited a >5% increase in CO2 rebreathing over the baseline measurement, a value that falls within a concerning range reported in the human study. A different study found that motor behavior response to increasing levels of CO2 begins when CO2 reaches ~3.1% (Lijowska et al., 1997). This means that an infant would work to move out of the dangerous breathing scenario when CO<sub>2</sub> rebreathing increases past 3.1% (or ~7.1% in our testing with the ~4.0% baseline). Looking at the On Slat results from our testing, roughly half of the products exhibited at least a 3.1% increase in CO<sub>2</sub> over baseline, suggesting that infants would seek to self-correct into a safer breathing position to avoid suffocation. However, external factors may prevent self-correction, particularly if an infant is wedged against a product or becomes entrapped, preventing otherwise free movement. It is also critical to note that we do not fully understand how the results of the rebreathing testing relate to a reallife scenario, but we hypothesize our results could be interpreted using the aforementioned logic.

The rebreathing testing we conducted was not without challenges. One consideration for this current test method is the sensitivity of the orientation of the infant face. As is, this testing method has a lower repeatability compared to tests incorporated into standards. Improving upon the probe shape would eradicate some of the variability of orientation. However, the goal of this testing was to better understand the most hazardous suffocation scenarios in order to inform standardized tests, so the variability within this testing is not a significant concern. A second consideration relates to the lack of a dynamic response to increasing CO<sub>2</sub> levels that is present in a human infant. When inspired CO<sub>2</sub> increases, ventilation also increases rapidly (Avery et al, 1963). This has real implications when considering the airflow alone. If an

infant requires more oxygen, he or she will try to inspire a greater volume of air in a shorter period of time. If a product does not allow for that airflow required by the infant, a suffocation scenario is in play unless the infant either arouses (if asleep) or can maneuver out of the position. The breathing rate and volume we used in this rebreathing testing did not change based on the amount of rebreathed CO<sub>2</sub>. We speculate that CO<sub>2</sub> rebreathing percentages would climb higher in a living infant scenario due to the increased ventilatory response if an infant cannot maneuver out of an unsafe position. Finally, the *rate* at which CO<sub>2</sub> rebreathing increases also affects the infant response, and our testing did not account for time to peak. Rapidly developing hypoxemia, for example, is more likely to generate an arousal response from an infant, while slowly developing asphyxia is less likely to cause arousal and therefore the infant would continue rebreathing CO<sub>2</sub>. As CO<sub>2</sub> creeps higher, the infant gradually becomes more and more acidotic (respiratory acidosis). So, it is possible that some products may contribute to a slow CO<sub>2</sub> buildup where progressive acidosis is possible. This scenario could be the most dangerous, as an infant would be less likely to arouse. Future research could consider the rate of CO<sub>2</sub> buildup and the impact on suffocation hazards.

## 5.5 CO<sub>2</sub> Rebreathing Recommendations

We understand that the complicated setup for these rebreathing tests are not suitable for a standard. However, we do believe the rebreathing data provides important information about these bumper and bumper-like products, and that understanding the relationships between rebreathing and other more easily testable measures has value. We offer no recommendations related to implementation of a rebreathing test method into a bumper standard, and instead suggest the changes to the airflow and firmness testing we presented previously are supported by our rebreathing testing. We also again suggest that the term "breathable" used for marketing purposes on some traditional bumper products (S03, S04, and S15) and mesh liners (S06 and S07) be removed considering the results of the CO<sub>2</sub> rebreathing testing did not necessarily differentiate these products from others.

# 6. Crib Climb-Out Testing

# 6.1 Crib Climb-Out Testing Overview

Caregivers have reported numerous incidents over the past 30 years of infants climbing or falling out of a crib, speculating that in those cases in which a crib bumper was present, a crib bumper might have played a role by acting as a step for the child. The purpose of this test method was to identify the height gained by an infant if he or she used the bumper like a step to help climb-out of the crib. The outcome measure of this study is height gained, and it will be discussed and interpreted in several scenarios.

# 6.2 Crib Climb-Out Testing Methods

We installed 18 bumper and bumper-like products previously described, excluding the vertical bumpers, onto a standard crib without a crib mattress and applied a load equivalent to the weight of a small 9-month-old infant to three areas of each bumper: directly between two crib bumper attachment points between slats, on or directly adjacent to a bumper attachment between slats, and on a slat where the bumper is attached. For mesh crib bumpers, there was an additional location in the corner of the crib, selected as a potential firm location of interest based on the hook-and-loop attachment system. After trial and error, it was determined that testing directly on a slat was not possible with the mechanism we developed. Thus, we tested in two locations for most products, depicted in Figure 23-left. The decision to have no crib mattress in the setup was made so that the deformation of the crib bumper under a given load was an *isolated variable*, unaffected by the crib mattress/bumper interaction which could be different based on the mattress/crib/bumper configuration. Vertical bumpers were not included in testing because the product does not bridge the gap between crib slats for which our test was designed. Additionally, no vertical bumpers were mentioned in any incidents we reviewed that reportedly involved climb-outs.

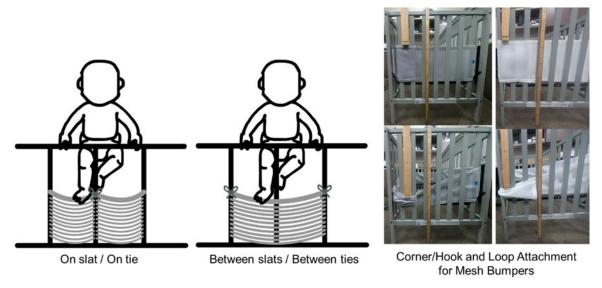
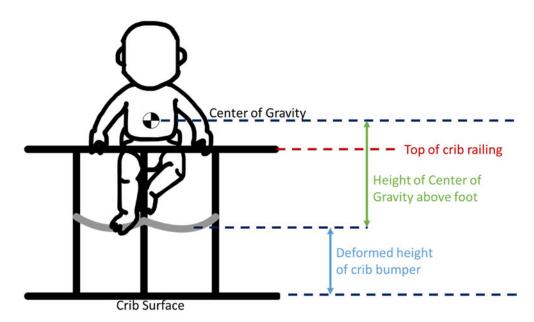


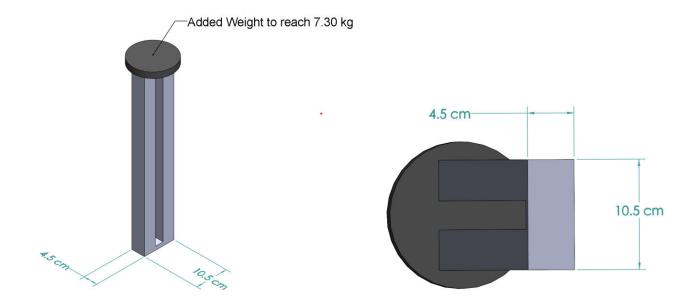
Figure 23: Testing locations for climb-out testing.



**Figure 24**: Schematic of climb-out risk assessment, where deformed height of crib bumper is termed "height gain".

The total height gained if an infant were to apply his or her entire body weight to that bumper was the outcome measure "height gain" (Figure 24). We assumed that the infant would place their entire body weight onto a single foot. We created a custom testing device based on the 3<sup>rd</sup> percentile weight of a 9-month-old (~7.3 kg) (CDC, 2000) and a contact area and rectangular shape resembling the foot of a 7-to 9-month-old infant (10.5 cm length x 4.5 cm width) (Snyder, 1975) (Figure 25). A small 9-month-old child was chosen as a conservative estimate for the anthropometric input values, as a child with a lower

weight would deform the bumper less than a heavier child. The age range was also chosen to represent the youngest infants who could be capable of climbing out of a crib and have reportedly been involved in such climbing incidents.



**Figure 25**: 9-month-old equivalent load for bumper deformation testing (contact area approximately equivalent to foot surface area).

To assess the height gained for each product under the applied load, we developed a custom MATLAB (The MathWorks, Inc., Natick, MA) code, utilizing the "imread" and "ginput" functions. When an image file is read into MATLAB, MATLAB sets each image pixel as (x,y) coordinates. As demonstrated in Figure 26, the code asks user to pick two points 10 cm apart on the scale, and two points at the top and bottom of the crib bumper when it is deformed under the load of the testing device. Based on the scale set with a known pixel distance correlated to 10 cm, the height gain (i.e. deformed bumper height) is generated in cm. The height gained outcome measurement could be done visually without much loss of accuracy, or we could develop a free image-based analysis program using ImageJ for open access.



**Figure 26**: Demonstration of testing protocol, and MATLAB Image Analysis schematic for bumper deformation testing using 9-month-old equivalent load.

## 6.3 Crib Climb-Out Testing Results

Many products tested deformed significantly under the load, resulting in minimal height gain which could contribute to climb-out scenarios. For traditional bumpers, 10 of 13 products resulted in < 6 cm of height gain. The ties on many of these products broke during testing, causing the bumper to collapse upon itself. However, 3 of 13 traditional bumpers performed differently, resulting in more height gain (S13: 9 cm, S16: 7.3 cm, and S20: 26 cm). In both conditions, S20 demonstrated minimal bumper deformation, resulting in height gains of 18 cm and 26 cm (Figures 27 and 28). The mesh bumpers (S06 and S07) resulted in larger height gains than most other products when we considered various testing locations. S06 had an added height gain of 18 cm when tested between attachments, and S07 exhibited 11 cm of height gain in the "on attachment" location. Of note, the braided product (S08) and lounger products (S11 and S12) exhibited height gained measurements of 10, 6, and 9 cm, respectively.

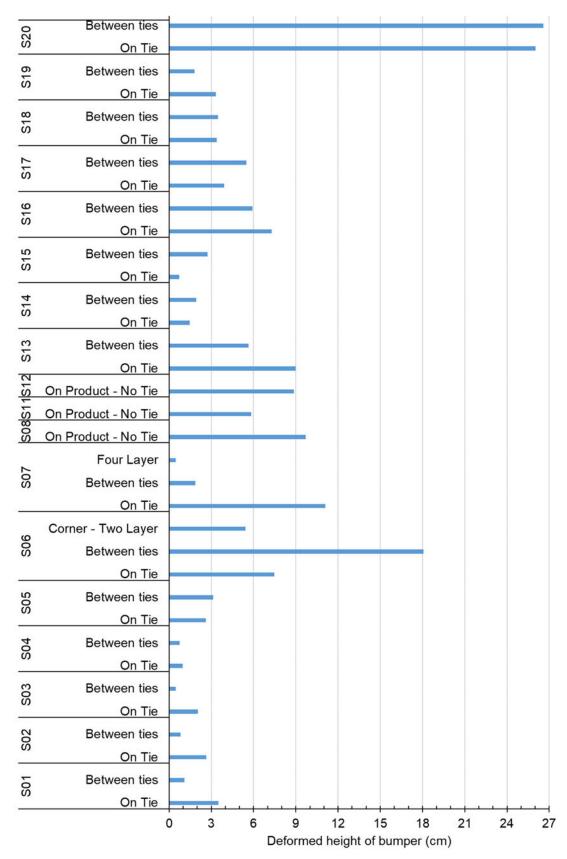


Figure 27: Climb-out testing results showing the deformed height (height gained) under the load.



**Figure 28**: Testing photos of the least deformed products (S06 between attachments, and S20 in two locations).

# 6.4 Crib Climb-Out Testing Discussion

Most traditional bumpers deformed significantly under a load and did not contribute more than a few centimeters to height gain. Firmness of the bumper also played a role in height gain. The firm and thick traditional bumper product (S20) resulted in the most height gained of all products tested. S20 featured a thick foam and passed all firmness tests. It makes sense, then, that this product would result in the most height gained since the product is firm enough to not deform much under a load, and thick enough for an infant foot to apply force against without collapsing onto itself. Interestingly, while firmness is a desirable characteristic for preventing suffocation, it is likely a contributor to climb-out risk.

Mesh products, due to the tautness of the nylon lining, also contributed to significant height gain, despite featuring no "firmness" according to previous testing and exhibiting very low thickness. During testing, a few bumper ties tore away from some traditional products under the applied climb-out load. Even if these products passed a tie strength test, the additive loads from the tension of installation and the climb-out model likely surpassed the load required for tie-strength testing.

We also observed that the relationship between attachment mechanism and climb-out height may be of interest, where products with more attachment-crib contact area such as mesh bumpers featuring the length-wise hook-and-loop attachments likely resist sliding under the climb-out load. However, the coefficients of friction between the attachment mechanisms and crib were not quantified in this study. Observationally, most products did not return to their pre-deformed shape after testing. The exception to this is S20 (the foam traditional bumper), S08 (the braided bumper), and S09 and S10 (the lounger products). We did not study additional hazards that may present themselves as a result of a deformed or broken bumper following a failed climb-out attempt, but observationally, many bumpers were loose or ties were broken after testing which likely presents a dangerous suffocation scenario.

To better explain the influence of crib mattress setting in interpreting the data, we offer an example of a crib setting at the lowest level and at the highest level. Gross infant anthropometric data (of a 9month-old infant in this case) was utilized to see if that height gained from the crib bumper increases the potential of the center of mass to cross the vertical "plane" of the crib side would give an indication of risk of climb-out associated with the crib bumper. Parameters related to a 9-month-old infant's height and center of gravity were obtained from published literature. The 3<sup>rd</sup> percentile length (height) of a 9-monthold infant is about 66 cm (CDC, 2000). For infants in the first year of life, the location of the center of gravity above the foot is about 56-58% of their height (Snyder, 1975; Swearingen, 1969). We used 56% of a 3<sup>rd</sup> percentile 9-month-old infant's height (i.e., 37 cm) as the location of the center of gravity. With our representative 15 cm thick mattress placed in a representative crib, the distance from the top of the crib railing to the top mattress surface in the lowest and highest crib mattress settings are 54 cm and 39 cm, respectively. If we ignore mattress deformation, the infant's center of gravity (37 cm) would be almost equal to the distance of from the top of the rail to the highest crib level (39 cm), meaning a risk of climbout (or fall-out) may exist without any added height from a bumper. Using the same center of gravity but at the lowest setting (54 cm), the added height gain from two products we tested would contribute to an increased risk of climb-out if an infant were to use the bumper as a step, The mesh liners, select traditional bumpers, the braided bumper, and the loungers may serve as a step for some infants, assisting them in climbing out of a crib.

Vertical bumpers were not able to be tested using this method. Our test assumed an infant would most likely use the space between slats to insert their foot on top of the top portion of a crib bumper, and the methodology did not allow for On Slat testing. Thus, the design of the vertical bumpers does not allow for this type of climb-out scenario.

The crib bumper climb-out testing elucidates the idea that tension between and a secure attachment to slats of the crib may introduce unintended risks to the sleep environment. While these characteristics are generally positive for preventing suffocation-related events, they are likely negative for other hazardous scenarios. Not only do products that feature observationally higher tension between slats contribute to height gained in a climb-out scenario, it is also likely that they will contribute *more* to an accidental entrapment scenario if infant gets their arm, leg, or even head, stuck between the bumper and the crib side compared to products with less tension. For example, if a baby's leg becomes entrapped in a product which is tightly secured to a crib, then the baby will require more effort to free the leg compared to a product with a looser attachment. However, it is also likely that the entrapment event itself is less likely due to the tension, meaning the baby would require more effort to get stuck in the first place. So, while it is possibly more difficult for a baby to become entrapped in a crib bumper that features a tight

attachment compared to a looser attachment, it is also likely more difficult for a baby to self-correct if they do become entrapped.

The methods developed in this study are conservative in the way we represent a small infant who would deform a product less and thereby achieve more height gain than a heavier and larger infant. We also chose to conduct this testing on a slatted crib rather than a solid panel crib side, assuming that the infant would be better able to balance a foot on top of the bumper between crib slats compared to a solid panel crib. The testing mechanism is easy to manufacture, and the methodology is straightforward. However, we have not developed a threshold for a "safe" height gain, mostly due to the variability in crib situations. As described in our example above, at high mattress settings or with taller infants, the infant's center of gravity may already be above the crib railing which would make any height gained from the bumpers less relevant considering the infant could fall over the rail without any additional height assistance. Furthermore, we know that infants climb out of cribs without any assistance from a crib bumper or other product, and this test method does not account for various coordinated movements or upper body strength which would contribute to crib climb-out potential.

A combination of tension in the lining or seams of the product, firmness of the product (exemplified by S20), and attachment mechanism (hook and loop for mesh liners) are likely the three characteristics that impact height-gain and increase the likelihood for climb-out events.

## 6.5 Crib Climb-Out Recommendations

The test method and analyses we developed are easy to manufacture and are based on anthropometric (height and weight) data of a conservative scenario for a 9-month old climb-out event. Threshold values could be further explored. However, there appears to be a trade-off in safe product firmness levels, where a firm product is desirable from a suffocation perspective, but a less firm product may be more beneficial in the context of preventing added height which could contribute to a climb-out event. A product that is firm in one dimension, and less firm in another dimension, may be optimal. If variable firmness is not possible, perhaps an ideal bumper height could be explored to to decrease the height gained for climb-out events even in firm products. Additional scenarios presented from a climb-out attempt were not explored, but it is likely that additional suffocation hazards may be presented by loose or broken bumpers after a failed climb-out attempt. Furthermore, human subjects testing is recommended to characterize the mechanisms of climb-out more fully. Finally, tie-strength testing could be revisited to account for both tension from the product installation and application of a climb-out load.

# 7. Alternative and Advanced Methods

### 7.1 Alternative and Advanced Methods Overview

Based on the results of our previous testing, ideas conceived through a literature review, trends in the IDI summary (Appendix A), and our own engineering and medical backgrounds, we explored new ideas for testing and evaluating bumpers and bumper-like products. We explored alternative firmness testing, rebreathing enhancements, conformability testing, and advanced combination (airflow plus firmness) methods.

## 7.2 Firmness Testing Alternatives

While the pass/fail test using a standard probe is relatively easy to implement, we feel the measure of firmness could be quantified more robustly in engineering terms using a force vs. displacement type of curve. Although a pass/fail test is useful in the context of a standard test, it does not inform manufacturers how to design products and select materials that pass such a test easily and optimize product safety. Since firmness appears to be an important parameter with respect to safety, it would be helpful to answer the question: What is the product's measure of firmness?

We selected 2 traditional bumpers which both passed all firmness tests (S04 and S20) and a traditional bumper which failed all firmness tests (S16) for a proof-of-concept study and found the force vs. deformation curves using a calibrated vertical lifter mechanism (Leshner & Associates, Inc., Elkton, MD) and a weight scale (Figure 29). The results show clear differences between the firm products (S04 and S20) and the product which failed all previous firmness tests (S16) (Figure 30).

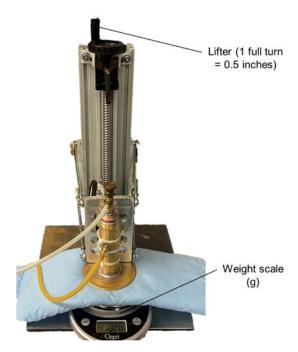
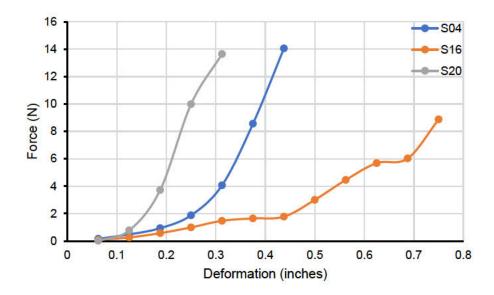


Figure 29: Vertical lifter mechanism and weight scale setup to assess force vs. deformation.

Using this type of common engineering measurement (force vs. deformation), we can characterize materials based on their deformation in a more robust way compared to a single pass/fail test. If we move forward with this method, we can consider anthropometric inputs as threshold values or improved probes. For example, a hemispheric probe similar in size to an infant nose shape incorporated into this simple test may give us an even more realistic measure of firmness in the context of a crib bumper in contact with an infant face.

One final thought regarding firmness of a crib bumper product is that, theoretically, if a product is sufficiently firm, do thickness or airflow characteristics matter in preventing a suffocation hazard? We explored this method in greater detail as part of advanced testing with many products in Section 7.



**Figure 30**: Force vs. deformation curve for 3 products: S04, a traditional but thin bumper which passed most firmness tests; S16, a traditional bumper which failed most firmness tests; and S20, a traditional but foam-filled bumper which passed all firmness tests.

This force vs. deformation method is similar to finding a "spring constant" of the product, where a greater slope represents a firmer surface, and a lesser slope represents a softer surface. The benefit of this method over a more simplified pass/fail test, is that we can begin to see the range of behaviors of products within the class. Additionally, we can quantify the deformation of the product at a given force using this method. Thus, with anthropometric inputs for infant nose depth, we can identify the force required to deform the product to that depth, which may lead to a more justifiable threshold value. We could also consider improving the probe shape to better represent an infant nose. Finally, to further characterize the products, we could measure airflow at each load or displacement, offering either a combined technique to characterize the airflow and firmness simultaneously of each product or to develop a firmness slope vs. airflow plot with defined areas of safe and unsafe products (described below in Section 7.4).

# 7.3 Conformability Testing

## 7.3.1 Conformability Testing Overview

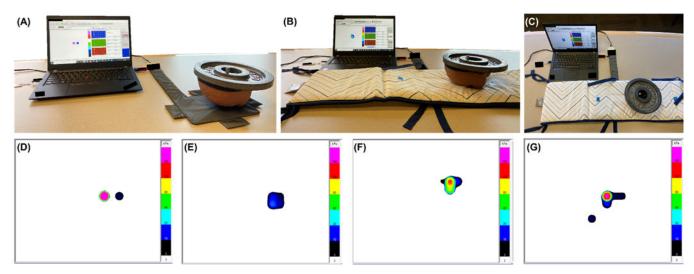
While firmness of a crib bumper product is certainly related to the likelihood that the product will conform around an infant's face, the two concepts are not exactly the same. Firmness (as measured by the flat disk devices shown in Section 3, is a rough pass/fail measure of force vs. material deformation, while conformability considers the likelihood of the material to conform to a particular shape. In the context of crib bumpers, a bumper that conforms to an infant's face likely causes a seal around the mouth and nose. Coupled with a product with lower airflow or higher CO<sub>2</sub> retention, this scenario would be a worst-case condition for suffocation. While our recommendations for the firmness testing in Section 3 do account for some degree of conformability, we believe this is an area that could be further explored. A measure of *how* the product deforms under a load rather than a simple pass/fail firmness test may provide more relevant information in the context of suffocation hazard.

We noted the CPSC staff's pilot testing of a more anthropometrically based nose/mouth probe in an attempt to measure conformability and firmness. While the CPSC team observed "voids" between the top edge of the device and the product during testing, it was impossible to tell if those voids descended into what would be the nose/mouth area of an infant which would allow for a channel of air to flow. Further, quantification of such voids was not described. Therefore, we piloted and propose a few new ideas to address this concern.

### 7.3.2 Conformability Testing Methods

To demonstrate our concept, we used 2 representative samples in the traditional crib bumper category (S02-passed firmness tests; and S16-failed firmness tests) and 1 sample from the mesh bumper category which passed most firmness tests likely due to the thin nature of the product (S07).

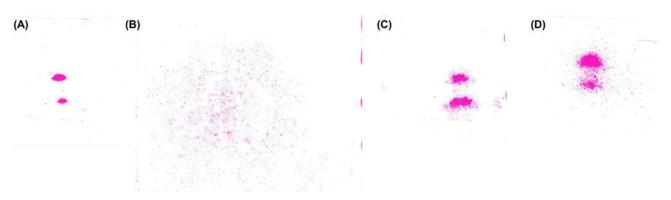
Two different measurement techniques were used to visualize conformability: a high-tech and state-of-the-art pressure sensing system (Novel, Inc., St Paul, MN) and a lower-cost and low-tech alternative pressure-sensing film (Fujifilm). A doll head with rigid facial features was used in combination with a 5 lb. weight (total weight: 5.8 lb.) to press into each of the 3 bumpers using each method (Figure 31 A, B, and C). The quantitative outcome variable from the pressure sensing system is total contact force (N), presented in Table 12, while the qualitative depiction of pressure distribution from the lower-cost pressure sensing film is presented in Figure 32.



**Figure 31**: Pressure sensing system conformability testing of the weighted doll head: (A) without any bumper, and (B and C) on a bumper. Pressure distribution is depicted below for: (D) the head/face only, (E) S02 – passed firmness, (F) S07 - mesh, and (G) S16 – failed firmness.

**Table 12**: Total contact force of representative traditional and mesh bumpers.

Sample	Total Contact Force (N)
Head/Face only	26.0
S02	3.8
S07	18.9
S16	18.7



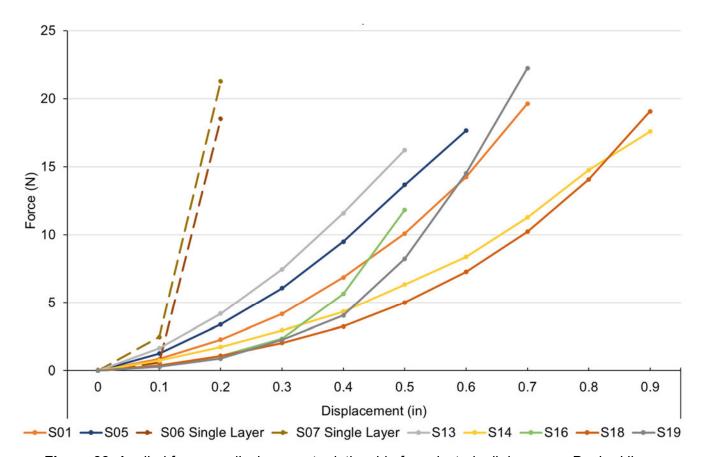
**Figure 32**: Pressure distribution output from pressure sensing film of: (A) head/face only, (B) S02 – passed firmness, (C) S07 – mesh, and (D) S16 – failed firmness.

## 7.3.3 Conformability Testing Discussion

The results of this pilot study demonstrate stark differences in force distribution between firm (S02) and soft (S16) traditional bumper products. The firm product (S02) dissipates the force across a larger contact area, such that the imprint of the infant nose and mouth is no longer distinguishable on the color maps (Figure 31E and 32B), and the contact force is less than 15% of the doll head. This is a stark contrast from the soft product (S16), where over 70% of the force from the doll head is concentrated in a localized region around the nose and mouth (Figures 31G and 32D). The mesh liner (S07) color maps and quantitative results are similar to S16, likely due to the thin and pliable nature of the mesh liner. Even though the product is thin, there is still conformability between and around the nose and mouth area indicated by the spots of color near the larger nose and mouth imprints. One limitation of this test is that it approximates the bumper on solid surface condition and does not consider conformability between slats. Our CO<sub>2</sub> rebreathing testing showed the risks of On Slat or Solid Panel CO<sub>2</sub> rebreathing are higher than the Between Slat condition, so we focused on the solid surface condition for this pilot testing. While no conclusions can currently be reached with this method of evaluating conformability, we hope to explore the idea further.

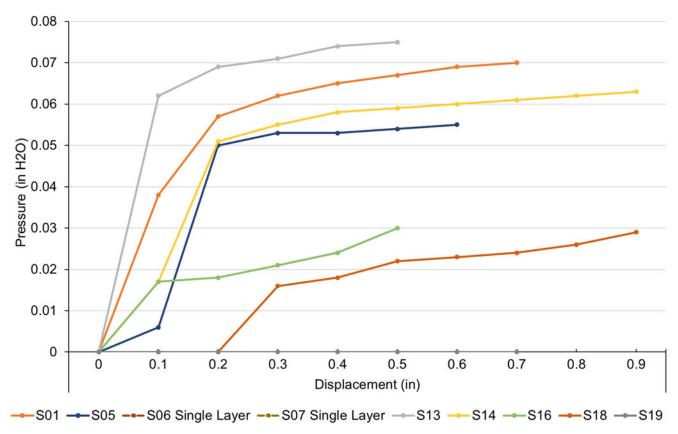
### 7.4 Combination Firmness and Airflow Advanced Testing

Using the fixture shown previously in Figure 29, we have combined test methods to describe both firmness and airflow characteristics in a single test on an unperforated platform, providing a more complete understanding of the relationship between force, differential pressure, depth of penetration, and airflow for crib bumper products. Products were deformed in 0.1 in increments, while force required for deformation *and* pressure drop via the modified airflow standard were measured. Figure 33 shows the force vs. displacement relationships, and Figure 34 shows the pressure drop vs. displacement relationships for all products.



**Figure 33**: Applied force vs. displacement relationship for selected crib bumpers. Dashed lines represent mesh liners.

The slope of each force vs. displacement line in Figure 33 is an indication of firmness. By quantifying firmness in terms of engineering measurements, firmness can be evaluated for its relationship to safety in view of other variables such as airflow and rebreathing.



**Figure 34**: Pressure drop vs. displacement relationship for selected crib. Mesh bumper data is not visible since both S06 and S07 exhibited 0 pressure drop for all tested displacements.

This detailed analysis of the inter-relationships between force, depth of penetration and airflow highlight significant differences between products, their materials of construction and performance under given loads. We could use this testing to determine threshold limits based on any parameter: displacement, force, or pressure.

#### Firmness vs. Airflow Plot

Another approach, rather than combining test methods, is to characterize the relationships between the separate firmness and airflow tests, then define combined thresholds for a safe product. For example, we assume that in a perfectly firm product, airflow characteristics are not a concern. Similarly, in a product that does not inhibit airflow (or retain CO<sub>2</sub>), firmness characteristics are not a concern for suffocation. Thus, this follows that there may be a combination of these two important parameters which uses thresholds of each test to define product safety from a suffocation perspective. In Section 7.2 above, we describe an idea to develop a force vs. deformation curve for each bumper. With this data, we would identify a critical deformation distance based on infant nose protrusion anthropometric data, find the slope of the best fit line, and call that value a pass/fail criterion. This idea could be further explored.

Our testing has revealed the even products that are firm, thin, and feature high airflow characteristics can become hazardous due to rebreathing when the product is doubled-over for attachment to the crib. Doubling or quadrupling the thickness of any bumper has implications for airflow, firmness, and rebreathing. Engineering measurements of firmness, airflow, and rebreathing could be applied to multiple layers of a product for safety research purposes.

### 7.5 CO<sub>2</sub> Rebreathing Testing: Incorporating Force

An unexplored aspect of CO<sub>2</sub> rebreathing is the quantification of the factors that may lead to the infant face and nares forming a strong "seal" with the crib bumper, particularly entrapment scenarios between the mattress and a crib slat. We utilized a pressure distribution measurement system (Novel Inc., St Paul, MN) attached to a crib slat to measure the maximum head contact force (N) experienced in a worst-case simulated wedging or entrapment scenario (Figure 35). We found the total head contact force to be 79.1 N (17.8 lbf) in our pilot testing, produced by the force of the deformed crib mattress pressing against the side of the infant manikin's head against the crib slat. While 17.8 lbf is likely very high even for a worst-case scenario, this pilot experiment demonstrates the high forces that an infant's head could feel in a wedging scenario. It is unlikely or even impossible that an infant could forcibly wedge their own head in this position in a functioning crib, however many incidents that we reviewed featured cribs with faulty drop sides or broken sides where an infant was able to wedge their head between the mattress and crib side. A scenario with a broken crib would likely result in a lower force that we measured during this representative test. We could consider using a force value representative of a dangerous wedging scenario in future rebreathing studies and in the context of previously discussed tests as appropriate.

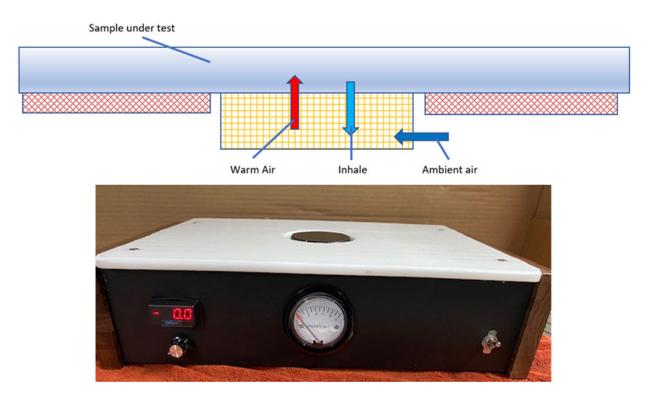


**Figure 35**: (Left) Simulated crib entrapment/wedging setup, and (Top Right) pressure distribution characteristics.

If we want to use this force of wedging data to inform future tests, we would like to repeat it with various sizes of heads and mattress types, representing a range of scenarios. This test was done as a representative example of how we could experimentally measure forces in various wedging scenarios.

### 7.6 Thermal Rebreathing Analyzer

The Thermal Rebreathing Analyzer (Figure 36) is a new tool for evaluating bedding materials for their relative effect on rebreathing, without using carbon dioxide. By equipping the device with a heater to warm the air exhaled from a sensing probe, carefully measured temperature differences are used to evaluate the level of rebreathing. The temperature difference serves as a proxy for CO<sub>2</sub> concentration. The operating principle is simple: infants exhale warm air and inhale cooler (ambient) air. A deviation in the temperature balance between ambient air and inhaled air is a measure of rebreathing exhaled air.



**Figure 36**: (Top) the thermal rebreathing analyzer discharges warm air into the sample under test. The temperature of the inhaled flow is compared to the temperature of ambient air; (Bottom) a differential pressure gauge on the front of the analyzer displays inhalation resistance.

Just as CO<sub>2</sub> from the exhaled breath can be stored in bedding and rebreathed, the same is true for warm air exhaled into the bedding and then returned to the "baby" at a temperature warmer than ambient temperature. The extent of rebreathing is indicated by the difference between the temperatures of the inhaled breath and ambient air temperature. When there is no rebreathing, the inhaled breath temperature will be equal to ambient temperature. As rebreathing increases so will the temperature of the inhaled breath, relative to ambient temperature. In other words, elevation in inhaled air temperature above ambient is a measure of rebreathing. A product sample is measured by laying it onto the measuring platform and applying a constant force. Figure 37 shows an example using a perforated platform (weighing 2552 g or 25.1 N force), though we also hope to explore an unperforated platform consistent with our recommendations for airflow testing and results of CO<sub>2</sub> rebreathing testing which show the On Slat or Solid Panel conditions are the worst-case scenario. The thermal rebreathing analyzer never requires calibration. The sensor is based on the properties of thermocouple alloys used in the construction of the actual sensor. Each 0.1 increment on the digital indicator is equal to a temperature difference of 0.0122 °C between the temperature of the inhaled stream and the ambient air temperature.

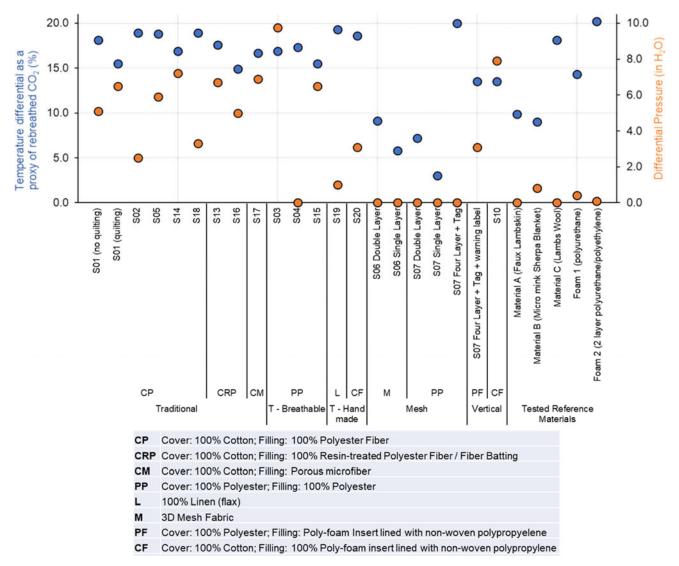


**Figure 37**: Thermal rebreathing analyzer with sample in place. Here we used a perforated (grate) platform, but we can explore an unperforated (solid) platform in the future.

Figure 38 presents the relationship between the recorded temperature differentials (blue) and modified BS 4578:1970 testing (perforated) pressure drop (orange) from all crib bumper samples and reference materials. Notably, the relationship for some products is not clear. Similar to the rebreathing data in Section 5, this new thermal rebreathing data does *not* apparently correlate well with the airflow testing results. This likely can be partially explained by the seal (or lack of seal) that is formed in the airflow testing, creating an air channel that results in no pressure drop for some products (mesh products, representative materials), while the rebreathing test methods do not rely as heavily on a perfect seal to give gradated results. So, while airflow testing, which relies on a perfect seal, is useful to differentiate between classes of products, some information (e.g. regarding CO<sub>2</sub> rebreathing) may be missing for products when a perfect seal is not possible (i.e. mesh products). Both rebreathing methods show a range of values for mesh products while the airflow testing results (<0.003 in H<sub>2</sub>O) alone is only able to differentiate between product classes. Rebreathing testing, while not suitable for standard implementation, could be further explored as a way to understand how products impact breathing.

Ideally, a correlation analysis between the CO<sub>2</sub> rebreathing values from the apparatus described in Section 5 and the temperature differential values obtained with the thermal rebreathing analyzer would be a good measure to assess whether the temperature differential method adequately predicts rebreathed CO<sub>2</sub>. However, the comparison of our previously collected data would not be equivalent since the inhaled air sensing probe on the thermal rebreathing apparatus likely has a good seal with the bumpers, being on a flat surface and loaded uniformly, while the CO<sub>2</sub> rebreathing apparatus manikin's face is uneven, has a rigid nose that may allow for the dissipation or loss of a certain level of rebreathed

CO<sub>2</sub>, and was unloaded during testing. in the future, we could establish the relationship between rebreathed CO<sub>2</sub> and temperature differential using similar flat surface probes for both test setups.



**Figure 38**: Combination test methods readings of temperature differential as a proxy of rebreathed CO<sub>2</sub> (in blue) and pressure drop from modified BS 4578:1970 testing (perforated) (in orange) from all crib bumper samples and reference materials.

## 8. Future Studies

### 8.1 Impact of Moisture on Suffocation Risk

In several suffocation IDIs reviewed by the team (Appendix A), moisture was observed near the nose or mouth of the infant victim. It is unknown how airflow or rebreathing is impacted by moisture on the product, and future work could explore this seemingly common scenario.

### 8.2 Individual Component Analysis

We only assessed each *aggregate* product. It may be beneficial to understand the contribution of each individual component of each product on parameters of interest (firmness, airflow, or rebreathing). It is likely that the material types, densities, and combinations of materials play a role in suffocation risk. If particular materials are identified that contribute to adverse product performance, product manufacturers and industry groups can be advised of the findings. Ideally, this research will help to reduce adverse events by advising manufacturers, regulators, and users. A detailed assessment for each of a product's materials of construction could help to identify potentially hazardous components in a composite product.

### 8.3 Conformability Testing Ideas

CO<sub>2</sub> rebreathing appears to be strongly related to the quality of the seal between the infant and the bumper. An unexplored idea regarding conformability involves imprint testing. In this method, we propose to paint a rigid doll face with grease paint, then press the painted face into each product at a given load. We would start with the weight of an infant head and increase to a force of a worst-case scenario when an infant is wedged between a mattress and a crib railing (example of 17.8 lbf derived from experimental testing in section 8.4). The benefit of this test method is that the voids that existed in the CPSC staff's pilot testing would be visualized via the imprint of the paint. A failed test would be one where the paint imprint on the bumper completely surrounds the nose and mouth, indicating a seal would form in that scenario. We could begin the pilot testing with a rigid infant doll face, then explore adding more realistic material properties.

# 8.4 Climb-Out Study Ideas

The limitation of upper body strength was not considered in our testing and using center of gravity is *not* the most conservative estimate for a "safe height" to prevent climb-out. No recent research has been

conducted on the coordinated movements contributing to crib climb-out using modern biomechanics technology. Without understanding crib climb-outs in a normal crib setting, it is difficult to decipher the role of crib bumpers to this hazard. An *in vivo* biomechanics study related to crib climb-out mechanisms in older infants and young toddlers would lend insight into how babies achieve this task, which would improve our understanding of how crib bumpers and other products might contribute to an increased risk for crib climb-out. Without a thorough understanding of the scenario, assessing risk from a product is difficult. In a 24-year-old study which observationally explored crib climb-out techniques, the authors state that "The application of motor development research to the design and evaluation on consumer products for infants and young children has been a neglected research area." (Ridenour, 1997). We agree with this idea and encourage future studies on movement-related tasks in infants.

### 8.5 Expanding the Knowledge Base

This study follows a history of adverse events associated with infant sleep products. After measuring the mechanical properties associated with a range of bumpers and bumper-like products, there is still much to be learned. The mechanical interactions between an infant's face and a product, whether firm or soft, is not well understood. It is our hope that these studies and those that follow will help to identify hazardous products and assist regulators and industry with the knowledge they will need to evaluate and develop safe products.

# 9. Summary and Key Points

- 1. The term "breathable" is undefined for infant products. We recommend the term "breathable" could therefore not be used to describe crib bumper or bumper-like products until a formal definition in the context of infant breathing is determined.
- 2. Crib bumper or bumper-like products should pass a firmness test. We recommend the same technique proposed by the CPSC with the product tested on a solid surface, with the difference that the product should **not** be secured to anything. Products should be tested in a worst-case scenario, meaning that products which feature multiple layers or overlapped layers when appropriately installed in a crib should undergo testing of multiple layers. All products should undergo firmness testing regardless of thickness. Future considerations could include a pre-tensioning protocol and a vertically-guided test fixture.
- 3. Crib bumper or bumper-like products should pass an airflow requirement in addition to the firmness test. We agree with the methods proposed by the CPSC using a modified version of BS 4578:1970. The testing should be performed on an unperforated support. The flowrate should be 2 L/min, based on physiological considerations. The threshold to pass the test should be < 0.003 in H<sub>2</sub>O. All bumpers or bumper-like products should undergo airflow testing, regardless of whether the product passed firmness testing. Locations of interest which include the thinnest and thickest portions of products with varying thickness, and any tags or warning labels which may be in contact with the baby should be tested. The limitation in requiring such a low threshold compared to measurement device accuracy and resolution could be remedied by decreasing the probe area.
- 4. Our testing has revealed that even products that are firm, thin, or feature high airflow characteristics sometimes still exhibited elevated CO<sub>2</sub> rebreathing results, especially when the product required multiple layers (e.g., doubled or quadrupled layers) for attachment to the crib. Doubling or quadrupling the thickness of any bumper has implications for airflow, firmness, and rebreathing. Measurements of firmness and airflow could be conducted on multiple layers of a product, when indicative of the worst-case scenario, for safety purposes.
- 5. The probe by which airflow testing and CO<sub>2</sub> rebreathing testing is conducted could be improved both by: (1) decreasing the area of the probe, and (2) conducting *in vivo* human subjects biomechanics testing to understand nose deformation under a given load. Decreasing the area of the probe would

require additional testing to establish a new and higher pressure threshold that distinguishes mesh liners from traditional bumpers.

- 6. The impact of moisture (mucus or saliva) on airflow and CO<sub>2</sub> rebreathing is unknown. Future studies could explore if and how outcome measures are impacted by this common scenario.
- 7. Climb-out testing for crib bumpers could be further explored. We developed a simple method based on anthropometric data, and we used it to assess bumpers and bumper-like products. A threshold value for safety could be further explored, as could implications of suffocation hazards introduced in a failed climb-out attempt which could loosen or break the crib bumper. Vertical bumpers likely pose a lower risk of climb-outs, similar to a bare crib, since the vertical bumpers we tested only cover individual slats and run the full height of those slats.
- 8. The coordinated movements by which infants climb-out of a crib is not quantified. Understanding these mechanisms through *in vivo* human subjects biomechanics testing may help to define a threshold for climb-out testing.
- 9. CO<sub>2</sub> rebreathing testing could be further explored as a way to better understand suffocation scenarios. While these more complicated measurement techniques may not be useful for implementation into a standard, further research could be done to understand how CO<sub>2</sub> rebreathing testing relates to more easily implemented testing.
- 10. Advanced methods which elucidate the relationships between force, deformation, and airflow could be further explored. Conformability to the infant face, and the impact of that conformability on CO<sub>2</sub> rebreathing is another area that warrants future investigation.
- 11. Based on our research on the range of crib bumpers and bumper-like products that we tested as part of this project, the following is a suggested list of characteristics for safe crib bumpers in the context of suffocation and climb-out prevention:
  - a. features no internal batting or filling,
  - b. mesh with no internal filling,
  - c. is firm in the horizontal (i.e. thickness) direction as to not conform to an infant's face,
  - d. is not firm in the vertical direction as to prevent significant "height added", though a threshold for safety to prevent climb-out events is yet to be defined.

While these characteristics would likely help prevent suffocation or climb out events, entrapment, entanglement, and wedging hazard scenarios have not been fully considered in the scope of this testing.

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# Appendix A – In-Depth Investigations

The team was provided with 103 In-Depth Investigation (IDI) packets which involved hazards, injuries, or deaths of infants or children when a crib bumper 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 employee summary of the investigation. The incidents spanned from 1991 to 2018. Of the 103 IDIs provided to the team, 82 were classified as deaths while 21 were considered hazards or injuries.

The goal of our IDI review was to summarize the data into an easily accessible table which included victim details, incident details, and crib bumper details. Drs. Mannen, Carroll, and Whitaker individually reviewed each IDI and provided a short interpretation of the incident. The CPSC employee interpretations of the incidents were not considered in our reviews. We asked the question "Would this incident have occurred had the crib bumper 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 bumper in the incidents with specific considerations in mind: Dr. Mannen focused on movement-related characteristics of the incidents, Dr. Carroll focused on medical conditions of the infants which may have contributed to the event, 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 bumper was *very unlikely* to have contributed to the incident, "2" meaning *somewhat unlikely*, "3" meaning *neutral*, "4" meaning *somewhat likely*, and "5" meaning the bumper 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 judgement on the contribution of the crib bumper to the reported incident. We did not indicate whether the crib bumper was the primary cause of the incident, only if the bumper likely contributed to the incident.

The crib bumper incidents presented a special challenge. Incidents were typically not witnessed, so for the purpose of the climb-out incidents in particular, the team relied on provided incident reports which often suggested the crib bumper provided climb-out support. Based on the results of the climb out

testing we preformed separately from this IDI review, some crib bumpers added several centimeters of height even under a compressive body-weight load, so we assumed throughout our IDI reviews that if a report suggested the crib bumper contributed to the climb-out event and if there was no information directly conflicting with the statement, that the crib bumper did contribute to the event.

After the preliminary reviews, if any of the three investigators scored the incident a 4 or 5, the incident was considered for further analysis.



**Figure A1.** Map of the continental United States showing locations of incidents where a crib bumper was likely or very likely to have played a role in the incident. Red points indicate deaths, while yellow points indicate injuries or hazards. There was one incident which occurred in Alaska that is not depicted on this map.

There were 49 IDIs (40 deaths and 9 injuries or hazards) that were scored *somewhat likely* or *very likely* to have contributed to the incident. Figure A1 shows the geographic distribution of the incidents. Events occurred in 28 states throughout the United States, in a mix of metropolitan and rural areas. The team determined the probable role(s) of the crib bumper in each of these incidents: suffocation and/or entrapment, and strangulation and/or climb-out. Suffocation and/or entrapment occurred in 38 incidents while strangulation and/or climb-out occurred in 11 incidents. **Table A1** shows a demographic breakdown of the incidents. Note that one infant in the suffocation and/or entrapment category was excluded from age analysis as the child was 43 months old at the time of the incident. This is a special case that we will consider later in the report.

**Table A1.** Demographics of incidents analyzed by hazard type.

Hazard Type	Number	Deaths/Injury or Hazard	Age ± SD (mos)	Male/Female	White/Black/Hispanic/Unknown
Suffocation &/ Entrapment	38	36 Deaths / 2 Injury or Haz	4.5 ± 2.2	19M/19F	27W/2B/4H/6Unk*
Strangulation &/ Climb-Out	11	4 Deaths/ 7 Injury or Haz	12.3 ± 4.3	8M/3F	2W/1B/1H/7Unk

\*more than 1 race/ethnicity listed for some

The incident analysis elucidated the suffocation and/or entrapment hazard impacts primarily younger infants within the 2 to 8 month range, while the strangulation and/or climb out hazard impacts older infants within the 8 to 17 month range. This makes sense, considering the developmental differences that the babies are experiencing in each of these age groups. The younger infants are less able to move themselves out of a potentially hazardous suffocation or entrapped position, while the older infants with more mobility are more likely to utilize the bumper in a way that is unintended in order to move around or out of the crib.

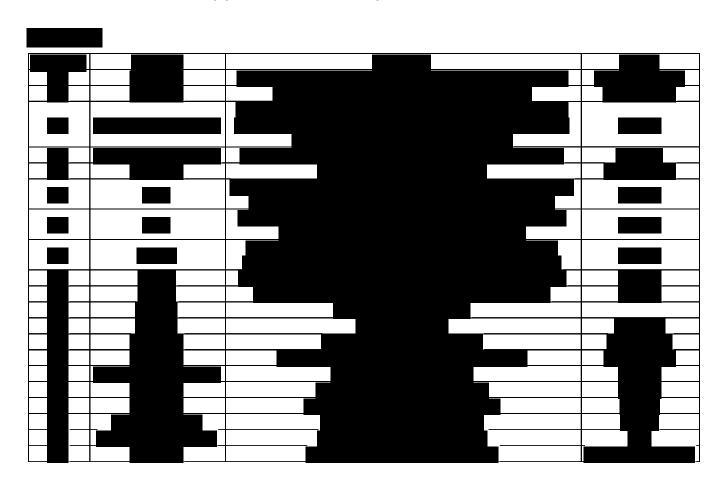
Some IDI packets provided brand and style information on the crib bumpers, and many also included photos of the products. In incidents where a photo or description of the bumper was provided, the crib bumpers involved in the incidents appeared to be traditional solid crib bumpers with a range of thicknesses estimated between ¼" to 2". There appeared to be no mesh bumpers, no vertical bumpers, and no braided bumpers in any of IDIs reviewed by the team.

Several incidents featured additional products that likely contributed to the deaths, injuries, or hazards: the product, the product, other sleep positioners, blankets or comforters, pillows, toys, drop-side or broken cribs, and other infant products. In incidents with positioners present, the infant often maneuvered partially or completely out of the product and found themselves entrapped between a bumper and the outside of the product. Based on results from previous infant inclined sleep surface research, it is possible that the incline angle of the products may have made it easier for younger infants to roll out of the product, entrapping them in a dangerous position between the sleep positioner and crib bumper. In the incidents included in this analysis, the infant's face was often found pressed against the bumper during these entrapment incidents, and the team judged that even in the cases where the positioner product may have caused the entrapment, that the bumper still contributed to the suffocation death. Broken cribs, both traditional and drop side, contributed to several incidents. Some parents reportedly used a crib bumper to "protect" the baby from a broken crib slat, which ultimately caused a strangulation event from the bumper which would have been avoided without the bumper present.

In infants with prematurity and / or underlying health issues, multiple variables contribute to adverse health-related events. None of the 11 babies who experienced strangulation and/or climb-out

incidents had any reported medical conditions. Of the 38 children who experienced a suffocation and/or entrapment incident, a few had health considerations. Five were born premature (<37 weeks gestational age at birth), two were twin births, three had heart issues either diagnosed prior to the incident or found via autopsy, and three had lung or upper respiratory conditions. A few IDIs also specifically mentioned that parents were influenced by healthcare professionals, friends and family, or advertisements to use an inclined product for infant sleep to alleviate acid reflux (both diagnosed and parent-perceived) for their baby. Other parents noted that similar products to the various sleep positioners were used in the hospital with their baby, and the parents wanted something similar for their home. One outlier (43-month-old female) had been previously diagnosed with cerebral palsy and was currently on sedating drugs at the time of the incident.

# Appendix B – Sample Identification



### Redacted

Sample ID	Category	Item Name	Vendor
S01	Traditional		
S02	Traditional		
S03	Traditional - "Breathable"		
S04	Traditional - "Breathable"		
S05	Traditional		
S06	Mesh		
S07	Mesh		
S08	Braided		
S09	Vertical		
S10	Vertical		
S11	Lounger		
S12	Lounger		
S13	Traditional		
S14	Traditional		
S15	Traditional - "Breathable"		
S16	Traditional		
S17	Traditional		
S18	Traditional - Used		
S19	Traditional - Handmade		
S20	Traditional		

# Sample photographs

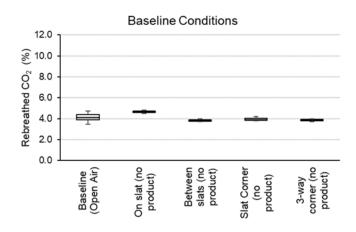


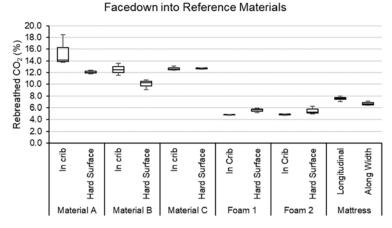
# Appendix C – Rebreathing Testing Results

This appendix contains the data from the CO2 Rebreathing Testing in all conditions tested. The most important findings were presented in Section 5, but all of the data is here for reference. Red bars indicate the product had failed firmness testing, while green indicates the product had passed firmness testing.

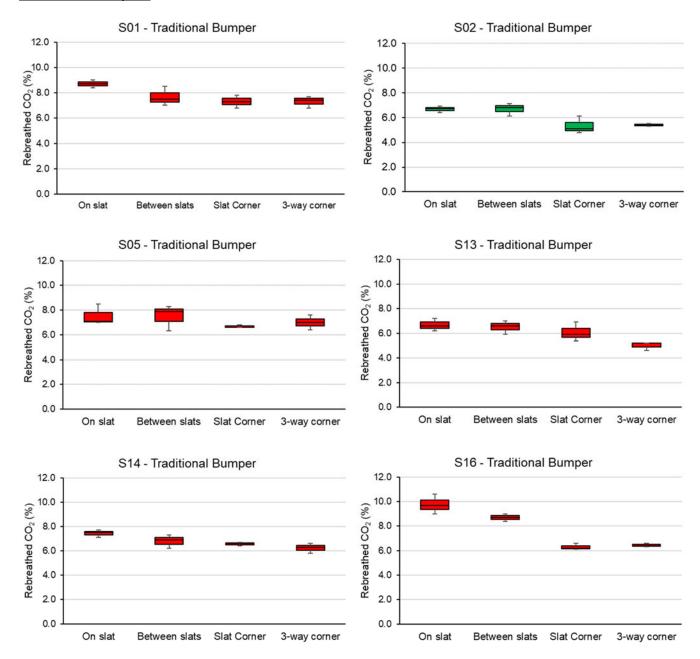
Slatted Crib

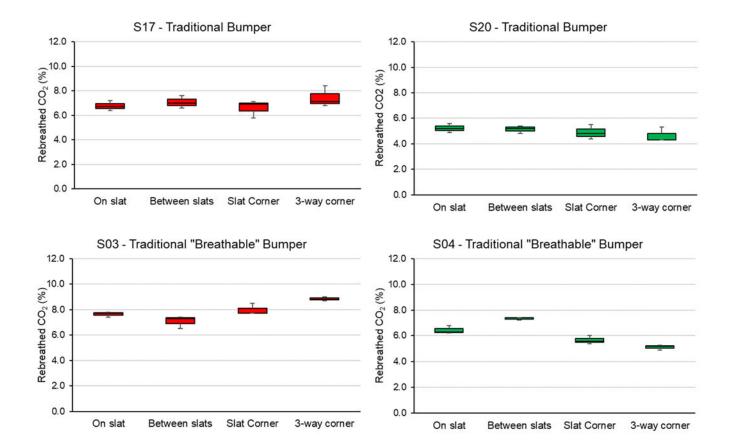
Baseline Conditions and Reference Materials

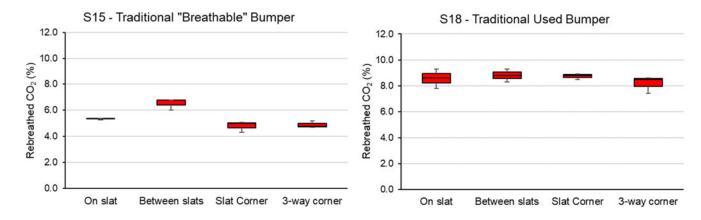


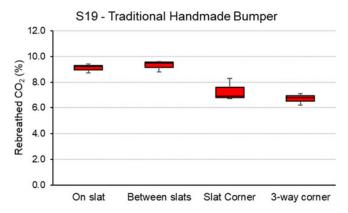


### **Traditional Bumpers**

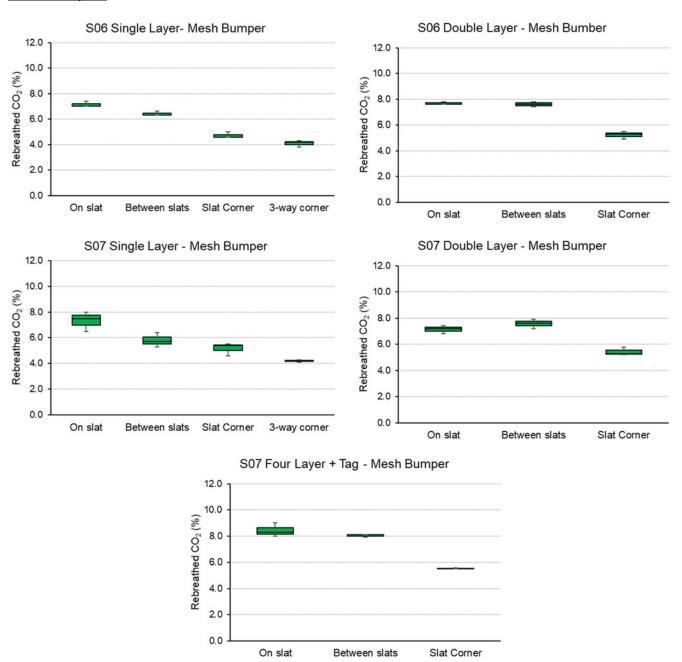




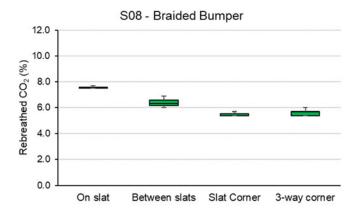




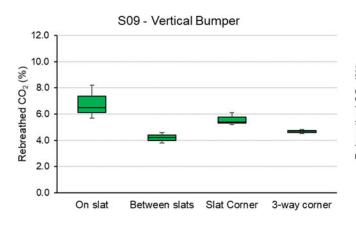
### Mesh Bumpers

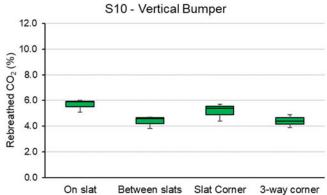


## **Braided Bumper**

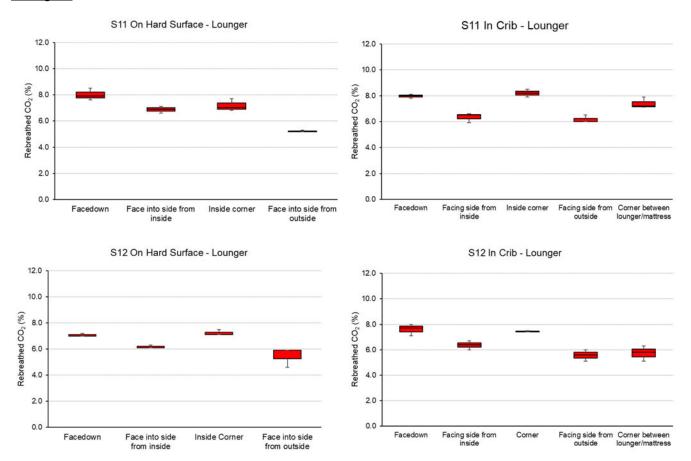


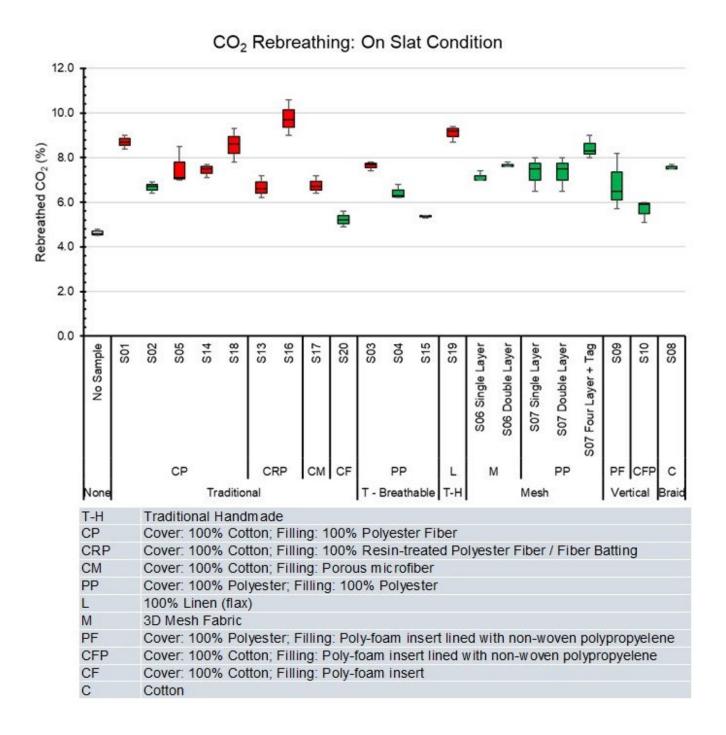
### **Vertical Bumpers**

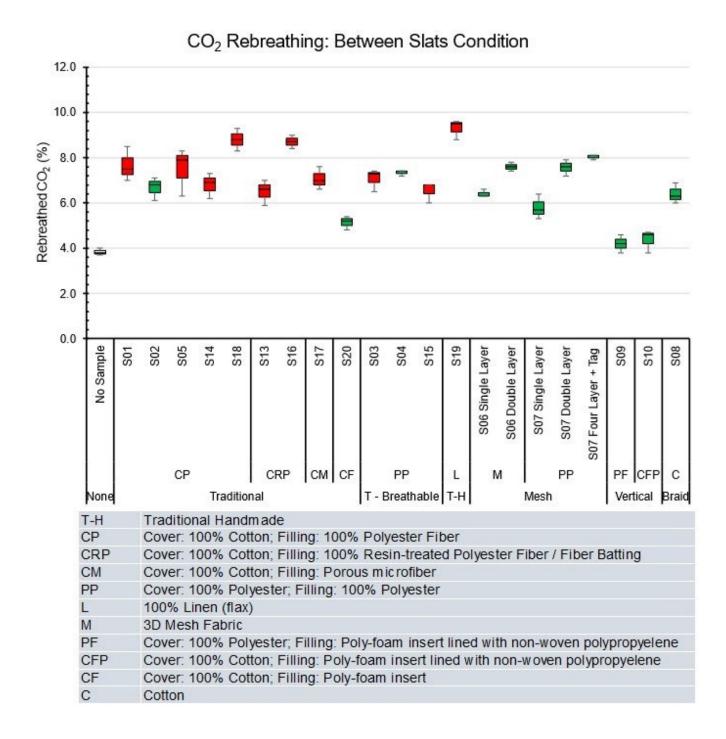


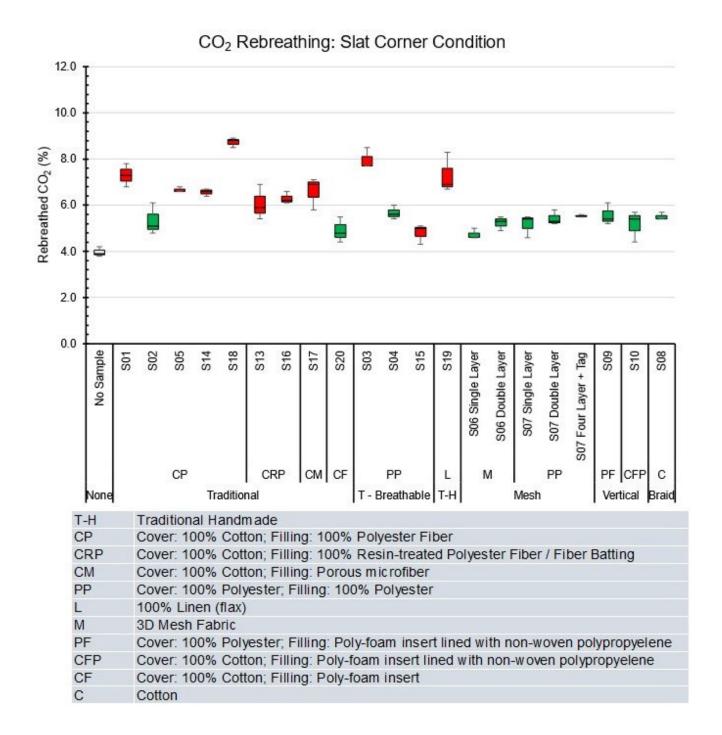


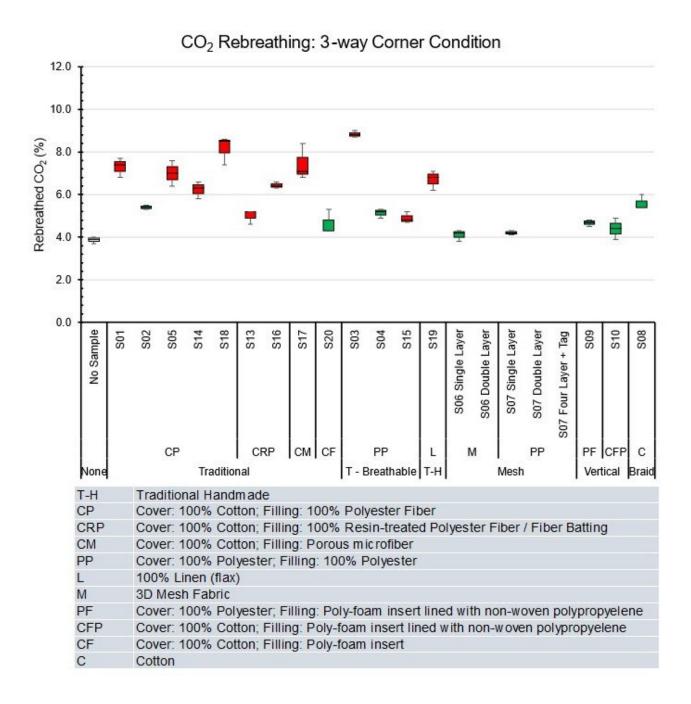
#### Loungers

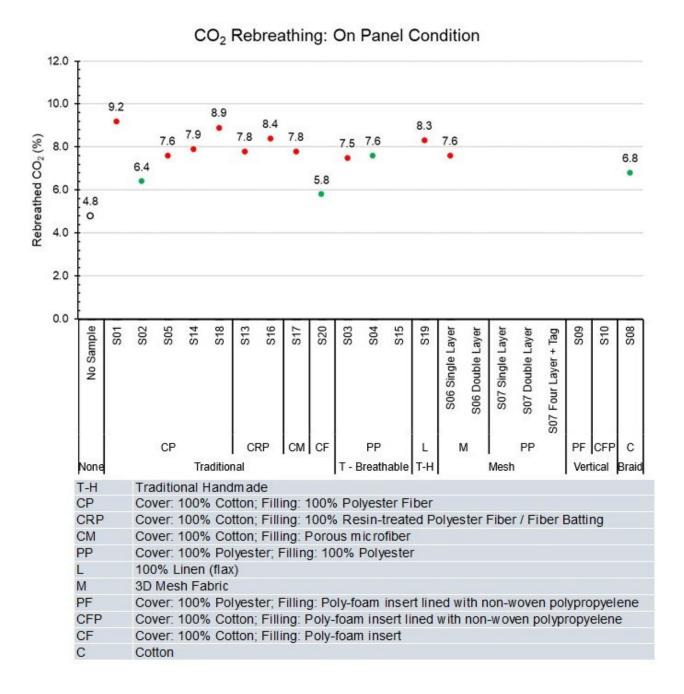


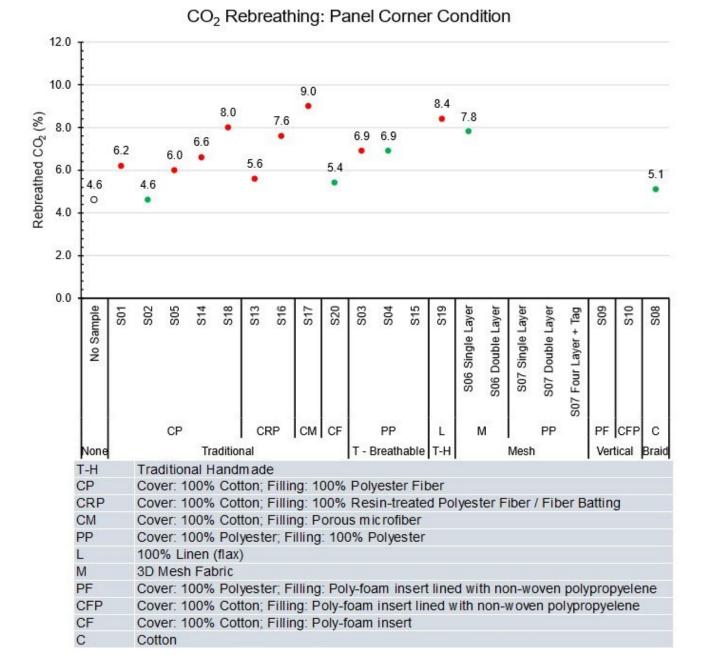












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