

## 1. Summary

This report provides results from testing conducted by the Bioengineering Department on the Anschutz Medical Campus in Aurora Colorado. Test procedures were adapted from the American National Standards Institute (ANSI) standard Z87.1-2003 [1] and guidelines compiled for the Journal of Occupational and Environmental Hygiene [2]. This test does not assess mechanical impacts.

### 1.1. Test Articles

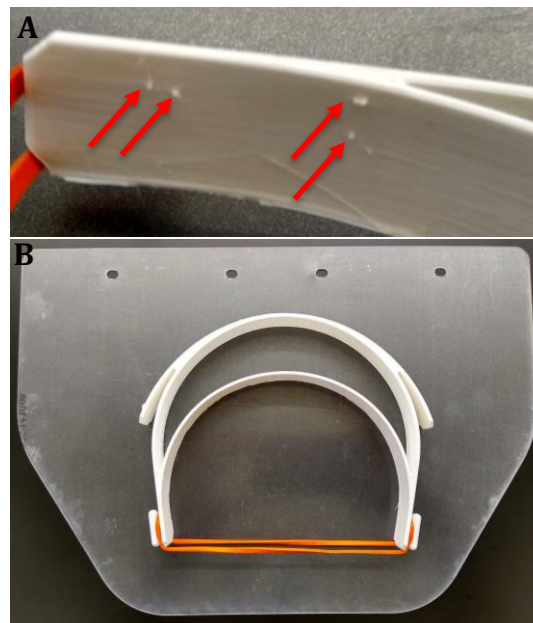
Test articles reported on are described in Table 1.

*Table 1: Test articles.*

Test Article	Part #/Lot #	Number of Samples	Material	Date
Prusa RC2/3 v2	Not Provided	2 Shields 2 Halos 2 Rubber Bands	PETG	4/8/2020

### 1.2. Results Summary

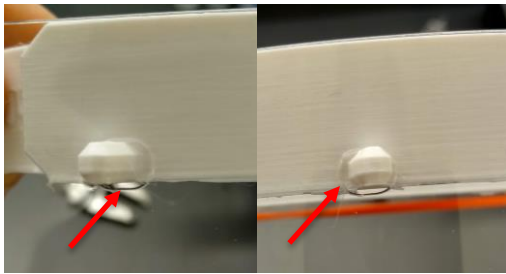
Results are summarized in Table 2. Specifications were derived from the ANSI standards and the clinical guidelines [1,2]. When the test articles arrived, there appeared to be manufacturing defects on the skin-contacting part of the halo (Figure 1a); they otherwise appeared as pictured on the submission form (Figure 1b). The shields studied were partially functional, demonstrating no flammability and no vision impairment or degradation after cleaning, but liquid penetration was observed during spraying. The shields tested demonstrated no shifting during use, but the rubber band made shield removal difficult due to catching of the tester's hair. The shields studied were not biocompatible, demonstrating skin irritation after a short period of use.



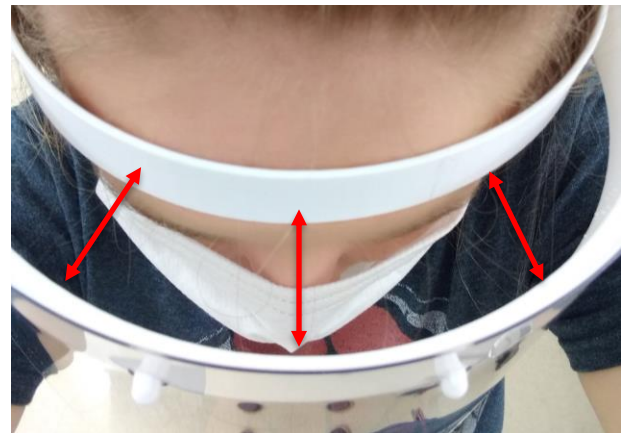
*Figure 1: Test article upon arrival.*

### 1.3. Recommendations

The tester spent a significant amount of the application time trying to peel the shield-covering films off. To improve ease of use and reduce user application time, it is recommended that the films be removed prior to shipment or that they be partially removed to facilitate quick removal in the clinical environment. To improve device functionality, multiple device openings should be sealed: the shield attachment points (Figure 2) and the gap between the forehead and outer halo (Figure 3). To improve biocompatibility, forehead padding would reduce redness and irritation. To prevent hair catching for user's with longer hair, an alternative elastic backing should be considered.



*Figure 3: Openings at shield attachment points.*



*Figure 2: Opening between forehead and outer halo.*



*Table 2: Test Results Summary.*

<b>Face Shield Test Matrix Summary</b>					
All standards per ANSI Z87.1 [1]. Methods are modified. Tests developed from healthcare face shield guidelines [2].					
	<b>Description</b>	<b>Specification</b>	<b>Test</b>	<b>Result</b>	<b>P/F</b>
Functionality	Flammability	Burn rate < 76 mm/minute	Expose to butane torch per ASTM 635	No flames observed, just melting	Pass
	Cleanability	No loss of vision or observed degradation	Clean with 70% ethanol, 10% bleach and Quaternary Ammonia solution.	No degradation or vision loss	Pass
	Spray Test	No penetration from colored water spray.	Spray shield from several angles with red colored water, assess for penetration	Penetration observed	Fail
	Visibility	No significant loss of vision	Perform standard eye test with and without, assess for change	No vision impairment	Pass
Biocompatibility	Biocompatible Material?	Is the material listed in the bill of materials known to be biocompatible?	Research	PETG is known to be biocompatible	Pass
	Irritability	Irritation of skin?	Tester feedback	Skin irritation and contact redness at forehead after 30 minutes, side head pain	Fail

Human Factors	Wear test	No shift in position greater than 3 cm	Perform typical nursing duties, assess for motion	No shifting during use	Pass
	Don/Doff time	Takes no more than 30 seconds to don or doff	Measure time	1.5 minutes	Fail

## 2. Results

### 2.1. Human Factors

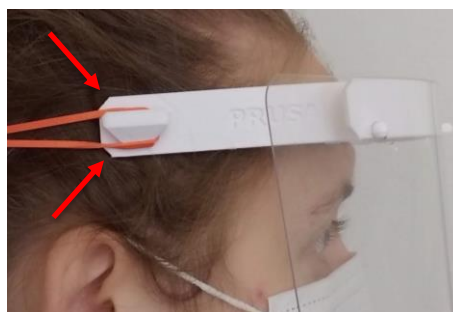
When moving the head side-to-side and up-and-down repeatedly, the shield did not shift. In the initial wear test up to 30 minutes, there was skin irritation and noticeable contact points from the shield (Figure 4). The tester experienced difficulties with donning and doffing with long hair catching on the rubber band and experienced pain at the halo end points (Figure 5).



*Figure 4: Tester's forehead after 30 minutes of wear.*

### 2.2. Spray Testing

After spraying the shield three times at eye-level from three sides, liquid penetration was observed on the forehead area of the test mannequin (Figure 6). It appeared that droplets made it over the gap between the forehead and halo (Figure 3).



*Figure 5: Location of head pain relative to halo.*

### 2.3. Cleaning and Vision

Three test solutions, 70% ethanol, 10% bleach, and a quaternary ammonia solution, were individually applied to the shield before a subsequent vision test. No damage, hazing, or reduction in vision was observed after cleaning the shield with the test solutions.



*Figure 6: Location of spray test liquid penetration.*

### 2.4. Flammability

When applying a butane flame to the shield material, no flames or burning were observed. The material melted but did not ignite. Burn rate was not recorded as no burning was observed.

## 3. Conclusion

The shield provided satisfactory visual quality, good cleanability, no flammability, and was easy to take on and off once sized to the user. The tester experienced

discomfort during wear and experienced hair catching when donning and doffing the shield. Openings in the shield allowed liquid penetration.

#### 4. References

[1] American National Standards Institute. "ANSI Z87. 1-2003 Standard Practice for Occupational and Educational Eye and Face Protection." (2003).

[2] Roberge, Raymond J. "Face shields for infection control: A review." *Journal of Occupational and Environmental Hygiene*, 13.4 (2016): 235-242.