

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
Make4Covid Titan Face Shield w/ Visor	Not Provided	2 Shields 2 Halos 2 V1 Visors 2 V2 Visors 1 TPU Band	PETG PETG PETG PETG TPU	4/20/2020

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 shields arrived, they were assembled according to the instructions for use (Figure 1). The shields

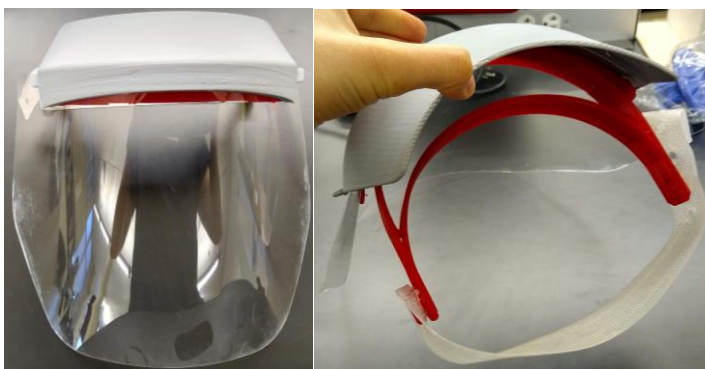


Figure 1: Assembled test article.

studied were functional, demonstrating no flammability, no liquid penetration during spraying, and no vision impairment or degradation after cleaning. The shields studied were not biocompatible, demonstrating irritation after 30 minutes of wear. The shields studied demonstrated no shifting during use, but both visor models popped off the shield during shield donning and doffing (Video in M4C Titan folder).

1.3. Recommendations

The tester attempted to remove the films with a razor blade (as pictured in the instructions for use) and accidentally cut off a portion of the shield edge. To improve ease of use and prevent damage, it is recommended that the film edge

is partially lifted for quick and damage-free film removal. To prevent the visors from popping off the halos during donning and doffing, a reduction in flexibility of the front portion of the halo is recommended. The tester experienced hair catching on the TPU band during wear tests. To improve usability, it is recommended that a non-sticky elastic securement method be used. To improve biocompatibility, it is recommended that padding be added to the forehead-contacting part of the halo.

Table 2: Test Results Summary.

Face Shield Test Matrix Summary					
All standards per ANSI Z87.1 [1]. Methods are modified. Tests developed from healthcare face shield guidelines [2].					
	Description	Specification	Test	Result	P/F
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	No penetration observed	Pass
	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 and TPU are known to be biocompatible.	Pass
	Irritability	Irritation of skin?	Tester feedback	Forehead irritation after 30 minutes	Fail
Human	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	10 seconds	Pass
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2. Results

2.1. Human Factors

When moving the head side-to-side and up-and-down repeatedly, the shield did not shift. Halo flexure caused both visor models to pop off the assembled system, which occurred during donning and doffing. In the initial wear test up to 30 minutes, forehead irritation and contact points were observed (Figure 2).



Figure 2: User forehead after use.

2.2. Spray Testing

After spraying the shield three times at eye-level from three sides, no liquid penetration was observed - no liquid was absorbed on areas protected by the face shield (Figure 3). Both visors models were tested and were functional.



Figure 3: Shield with visor model 1 (left) and visor model 2 (right) post-spray test.

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.

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 and good cleanability. The visors prevented liquid penetration, but were not stable during donning and doffing. The material is not flammable and is known to be biocompatible. The tester experienced discomfort during wear.

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.