

Face Shield Test Protocol

Face Shield

Dated April 24, 2020

1. Overview

The Face Shield is a device that helps to protect the clinician from biological contaminants. This document is the test protocol to conduct Human Factors Usability Validation.

Face shields can substantially reduce the short-term exposure of health care workers to large infectious aerosol particles, but smaller particles can remain airborne longer and flow around the face shield more easily to be inhaled. Thus, face shields provide a useful adjunct to respiratory protection for workers caring for patients with respiratory infections. However, they cannot be used as a substitute for respiratory protection when it is needed.

This protocol outlines a use validation which involves the evaluation of the Face Shield. This evaluation will be done by the intended end users of the face shield- health care workers and clinicians. The testing will be performed in a clinical setting the same as the expected use environment.

2. Test Conditions

This test protocol is to be conducted under test conditions that are identical to actual use conditions. This means:

- Test participants are representative of actual users.
- Environmental conditions are the same.

3. Data Collection

Data that will be collected for this usability test include responses to questions related to comfort, coverage, ease of use, durability and other customer requirements.

4. Participants

At least 15 participants will be included in this usability study. The sample size is based on published guidance from FDA-Applying Human Factors and Usability Engineering to Optimize Medical Device Design, Feb 3, 2016.

Compensation: No physicians will be compensated as part of this study. However, it should be noted that 15 are under contract with MGH.

5. Training

No specific participant training is anticipated for this study. The study objectives and expectations will be explained to the participants prior to their evaluation.

6. Environment

Participants will use the Face Shield under actual conditions that incorporate typical environmental conditions that could impact use. The study will be conducted in a hospital environment. No additional use settings are anticipated based on the device' use and its applicability.

7. Device Evaluation

For the evaluation of the face shield, the clinician will be asked to respond to a series of questions (Attachment 1) that are used to validate the customer requirements to be tested per this protocol. The participants will be asked to respond to each question twice; once for each all plastic face shield prototype. This will give the study a foothold to compare the two designs. These questionnaires focus on evaluating if the face shield meets the user needs and intend use.

Responses for questions will be in a ranking format, from insufficient to sufficient and documented on the response sheet. The questions have been developed to account for all failure modes from the FMEA. Additionally, certain questions also account for user preferences related to documented customer requirements.

8. Usability Tasks

	Requirement	Critical (Y/N)
1.	Comfort / Skin Irritation	Y
2.	Fit/Movement	Y
3.	Compatible with Stethoscope	Y
4.	Compatible with Instrument Use	Y
5.	Compatible with use of glasses or goggles	Y
6.	Visibility	Y
7.	Resistant to fogging	Y

9. Usability Acceptance Criteria

The results of the customer requirements must be an average of sufficient or above to be considered passing.

10. Reporting Results

A Test Report shall be generated at the conclusion of the test. It will consist of a report of the results, which includes an evaluation of the participant responses for the survey questions. Subjective assessments and (if applicable) specific use-related problems from participants will also be documented. The report may be a stand-alone document, or an addendum contained within the Human Factors Test Protocol. Completed forms and the test configuration record provided in this document shall be scanned and attached to the final report.

11. Test Samples

For this validation, a total of 15 samples of each design will be used. These samples will be manufactured at Dr. Jennifer A. Lewis' lab at the Wyss Institute and all components will meet all intended material, design and dimensional specifications for the product.

Attachment 1: Questionnaire

1. Gender: _____
2. Job Title: _____
3. How long did you wear the prototype for? #1: _____ HOURS _____ MINUTES
#2: _____ HOURS _____ MINUTES

CATEGORIES	PROTOTYPE FACE SHIELD #1 PROTOTYPE ID#: _____					PROTOTYPE FACE SHIELD #2 PROTOTYPE ID#: _____				
	INSUFFICIENT		SUFFICIENT		EXCELLENT	INSUFFICIENT		SUFFICIENT		EXCELLENT
<i>Comfort</i>										
<i>Fit</i>										
<i>Visibility</i>										
<i>Face Coverage/Protection</i>										
<i>Fogging</i>										
<i>Up/Down Range of Motion</i>										
<i>Left/Right Range of Motion</i>										
<i>Ability to Stay in Place During Quick Motions</i>										
<i>Don and Doff Procedure</i>										
<i>Compatibility with stethoscope</i>										
<i>Compatibility with general PPE</i>										
<i>Overall Impression</i>										
Would you be able to wear the prototype face shield for your entire shift? If not, why?										
What did you like the about the prototype face shield?										
Areas for face shield improvement (if any):										

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