Human Factors Validation Test Results

Face Shield

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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 document outlines the results of clinical evaluation from anticipated users.

2. Test Conditions

This test protocol is to be conducted under test conditions that are identical to actual use conditions. The test follows the protocol indicated in the document *Face Shield Test Protocol – Human Factors*.

3. Test Samples

For this validation, a total of 15 samples 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. The participants will also evaluate the out-of-the-box face shields currently used at the MGH (Critical Coverall).

4. Questions

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. The questionnaire as seen by participants can be seen in Attachment 1. In addition to the questions listed below the participants were also asked their job title and gender. This set of questions was asked to each participant. The first set of questions participants were asked to rate features on a 1-5 scale from insufficient (1) to sufficient (3) to excellent (5):

#	**Question**
1.	Comfort
2.	Fit
3.	Visibility
4.	Face Coverage/Protection
5.	Fogging
6.	Up/Down Range of motion
7.	Left/Right Range of motion
8.	Ability to stay in place during quick motions
9.	Do and doff procedure
10.	Compatibility with stethoscope
11.	Compatibility with general PPE
12.	Overall impression

Three additional questions were posed to evaluate only the prototype shield, where the participant was asked to write a response:

#	**Question**
13.	Would you be able to wear the prototype face shield for your entire shift? If not, why?
14.	What did you like about the prototype face shield?
15.	Other comments/areas for improvement (if, any):

5. Participants

The sample size of this test was given to be 15 participants (see Participants requirements in document *Face Shield Test Protocol – Human Factors*).

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

6. Training

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

7. 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.

8. Summary of Results

Participants in this study were residents and employees of the Trauma Surgery Department of Massachusetts General Hospital. 14 participants filled the surveys in total. A summary of average scores for the tested specifications is given in table below. Please refer to the full results of the prototype face shield in Attachment 2 and the Critical Coverall Face Shield in Attachment 3.

Specification	Lewis Lab all plastic Face Shield (average)
Comfort	4.0
Fit	4.1
Visibility	3.9
Face Coverage /Protection	4.4
Fogging	4.3
Up/Down Range of Motion	3.6
Left/Right Range of Motion	3.6
Ability to Stay in Place During Quick Motions	3.7
Don and Doff Procedure	3.1
Compatibility with stethoscope	3.4
Compatibility with general PPE	4.0
Overall Impression	3.6

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
Comfort										
Fit										
Visibility										
Face Coverage/Protection										
Fogging										
Up/Down Range of Motion										
Left/Right Range of Motion										
Ability to Stay in Place During Quick Motions										
Don and Doff Procedure										
Compatibility with stethoscope										
Compatibility with general PPE										
Overall Impression										

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):		

Attachment 2: Human Factors Test Raw Data, Lewis Lab Prototype: 4/10/2020

Category	Clinicia Clinician 2		Clinicia Clinician 5		Clinicia Clinician		Clinicia Clinician		Clinicia Clinician		Clinician 12		Clinician 13		Clinician 14	Clinicia Average
Gender	Male	Female	Female		Female		Female		Female		Male	Female	Male		Female	
Job Title	Resident	Resident	Hospitalist	MD	Resident	RN	Female RN	RN	Female RN	RN	Male RN	Female RN	Male RN		Female RN	
Face Shield ID	D.00099	D.00098	D.00097	D.00100	D.00112		D.00107	D.00107	D.00107	D.00107	D.00101	D.00095	D.00096			
How long did you wear this for? (min)	2	2	1	2	25 (kept for rest	-	12	10	5	5	25	5	5		1 -	6.4
Comfort	5	4	3	4	5	3	3	3	4	5	4	4	4		4 -	4.0
Fit	4	3	3	4	5	3	3	5	3	5	4	5	5		5 -	4.1
Visibility	5	3	3	4	4	4	3	5	4	5	4	5	4		3 -	3.9
Face Coverage&Protection	5	5	3	4	5	4	5	5	3	5	5	4	4		3 -	4.4
Fogging	5 -		5	4	5	5	3	5	3	5 -	3.5	5	5		3 -	4.3
Up/Down Range of Motion	5	2	4	2	5	4	3	2	3	4	5	5	5		4 -	3.6
Left/Right Range of Motion	4	4	5	2	5	3	3	2	3	4	3.5	5	5		4 -	3.6
Ability to Stay in Place During Quick Motions	4 -		3	3	5	2	3	3	3	4	5	5	5		3 -	3.7
Don and Doff Procedure	-	1	3	2	3	2	3	3	5	4	3		5		3 -	3.1
Compatibility with stethoscope	-	-	3 -		5	3	3 -	3	3 -		4 -				3 -	3.4
Compatibility with general PPE	-	-	3 -		5	5	3 -		3	4	4	4	4		4 -	4.0
Overall Impression	4 -		3	3	5	3	2	3	3	5	4	4	4		4 -	3.6
Would you be able to wear the prototye face shield for your entire shift? If not why?	Yes	Too much range of motion restriction	Yes	Limited range of motion	Glare makes typing a bit tricky	Slight echo, get used to it	No, too clumsy				No feels a little crowded	Yes	No, heat		-	
What did you like about the prototype face shield?	Also excellen t protectio n, Had better ROM	Lightweight, more up and down mobility	Comfort		I love that I can keep it on between rooms changing, no edges. Solidly stays on. Good all around protection	Feels more protectiv e					The overall protection	Covers head and face well	Stability, flexible band		-	
Areas for Face shield prototype improvement (if any):	More adjusta bility to sizing	Fastening	Better up/down moveme nt	Some glare around level of N95 (reflection), fine to adopt even as is		Donnin g							N/A		-	

Attachment 3: Human Factors Test Raw Data, Critical Coverall Face Shield: 4/10/2020

Category	Clinicia	Clinician 2	Clinicia	Clinicia	Clinician 5	Clinicia	Clinicia	Clinicia	Clinicia	Clinicia	Clinician	Clinician 12	Clinician 13	Clinician 14	Clinicia	Average
Gender	Male	Female	Male	Female	Female	Female	Female	Female	Female	Female	Female	Male	Female	Male	Female	
Job Title	Resident	Resident	Resident	Resident	Hospitalist MD	Resident	RN	RN	RN	RN	RN	RN	RN	RN	RN	
Face Shield ID	D.00099	D.00098	D.00097	D.00100	D.00112	-	D.00107	D.00107	D.00107	D.00107	D.00093	D.00101, D.00105	D.00095	D.00096	-	
How long did you wear this for? (min)	2	2	1	2	25 (kept for rest c		12	10	5	5 -		25	5	5	1 -	6.4
Comfort	5	4	3	4	5	3	3	3	4	5	5	4	4	4	4 -	4.0
Fit	4	3	3	4	5	3	3	5	3	5	5	4	5	5	5 -	4.1
Visibility	5	3	3	4	4	4	3	5	4	3	4	5	4	5	3 -	3.9
Face Coverage&Protection	5	5	3	4	5	4	5	5	4	5	4	5	4	5	3 -	4.4
Fogging	5 -		5	4	5	5	3	5	3	5 -		3.5	5	4	3 -	4.3
Up/Down Range of Motion	5	2	4	2	5	4	3	2	3	3	4	5	5	5	4 -	3.6
Left/Right Range of Motion	4	4	5	2	5	3	3	2	3	3	4	3.5	5	5	4 -	3.6
Ability to Stay in Place During Quick Motions	4 -		3	3	5	2	3	3	3	5	4	5	5	5	3 -	3.7
Don and Doff Procedure	-	1	3	2	3	2	3	3	3	5	4	3	5	5	3 -	3.1
Compatibility with stethoscope	-		3 -			3	3		3	3 -		4 -			3 -	3.4
Compatibility with general PPE	-		3 -		5	5	3 -		3	5		4	4		4 -	4.0
Overall Impression	4 -		3	3	5	3	2	3	3	5	4	4	4	4	4 -	3.6
Would you be able to wear the prototye face shield for your entire shift? If not why?	Yes	Too much range of motion restriction	Yes	Limited range of motion	Glare makes typing a bit tricky	Slight echo, get used to it	No, too clumsy				No feels a little crowded	Yes	No, heat	-		
What did you like about the prototype face shield?	Also excellen t protectio n, Had better RDM	Lightweight, more up and down mobility		Comfort	I love that I can keep it on between rooms changing, no edges, Solidly stays on, Good all around protection	Feels more protectiv e					The overall protection	Covers head and face well	Stability, flexible band	-		
Areas for face shield prototype improvement (if any):	More adjusta bility to sizing	Fastening	Better up/down moveme nt	Some glare around level of N95 (reflection), fine to adopt even as is	Donnin g								N/A	-		

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