

Appendix 10_A. Human Factors Validation Testing Report

1. Overview

The purpose of this human factors validation (summative) testing was to demonstrate that test participants representative of the intended users of the ClearMask, could perform all of the intended critical and essential user tasks, with the final device design and labeling. The human factors validation testing was conducted under simulated use conditions representative of actual task performance, without performance issues that would be indicative of flaws or inadequacies of the device.

The validation testing was conducted by the Company in a simulated use environment setting. Test participants across a representative user population performed the test scenarios. The comprehensive usability assessment included all critical knowledge and essential tasks previously identified in the use-related risk analysis, with a particular focus on:

1. Tasks associated with the donning, wearing, and removal of the ClearMask
2. Test participants' ability to understand the information within the Instruction for Use (IFU) material

For reference, the study materials listed below are provided as attachments to this report:

Material	Appendix Name
Study Protocol and Data Collection Form	Appendix 10_B ClearMask Human Factors Study Protocol and Data Collection Form

The researcher has completed all simulated use testing sessions with a total of nineteen (19) test participants.

2. Procedure

The sessions were conducted in an environment that simulates the expected use areas where the Device will be used. For each participant, the validation session followed the procedure described below.

1. **Welcome and Introduction:** A brief introduction to the session was provided. This included high-level summaries of the validation test objectives and process, the test moderator's role, the test participant's role and rights, along with general guidelines to follow during the test session.

- Environment Description:** A brief orientation to the test environment was provided for the enrolled test participants. The test participants were informed they had access to the materials needed while using the ClearMask.
- Training:** There is no training required for the use of the ClearMask. No training was provided to test participants.
- Task Performance:** Participants were asked to perform tasks representative of what they would do with the real device. In addition, participants were asked critical knowledge task questions. The test moderator asked the participants to perform these tasks using a script. An observer recorded performance results and observations on the participants' actions, knowledge, and feedback on a data collection form. A photo was taken of the device once it was successfully donned on the subject's face. The photo was with de-identified after the procedures prior to archival and storage.
- Interviews:** Participants were interviewed to gather feedback on the overall device, capture the participants' assessment of any use difficulties, confusions or errors that were experienced during the session, and collect the participants' assessment of root cause for any observed or participant reported use difficulties, confusions or errors.
- Wrap up:** At the end of the session, the participants were asked for any additional feedback and then thanked for their time.

A sample of the questionnaire and data collection form used during the study was provided in Appendix 10_B.

3. Simulated Use Environment

Validation testing was conducted at the Johns Hopkins Medical Institution. The test environment was a private office.

The private office was configured with a table, chairs, a digital camera, and overhead fluorescent lighting typical of a private office. Supplies necessary to complete all tasks were provided, which are listed in the Materials section below (Section 4).

4. Materials

The ClearMask materials provided include the ClearMask design and all components of the labeling:

- Packaging
- Instructions for Use (IFU)
- The ClearMask device

The ClearMask material provided was equivalent to production units.

5. Test Participants

A summary of test participants by Healthcare Provider Type and gender are presented in the table below.

Table 1. Test Participants by Demographic Factors

Gender (N = 19)		
	Number	Percent of Total
Female	8	42%
Male	11	58%
Healthcare Provider Type (N = 19)		
Physician	16	84.2%
Nurse	3	15.8%
Race (N = 19)		
White	3	16%
Black	4	21%
Asian	8	42%
Other/Refused	4	21%

6. Test Scenarios

Each test participant engaged in the following test scenarios:

1. Initial donning
2. Speaking
3. Removal

The test scenarios included all critical, critical knowledge and essential tasks previously identified in the use-related risk assessment. Scenario sessions were conducted in a private setting by a trained facilitator-observer team.

7. Results

The results of each task are summarized below. Observation data, participant responses to questions, and additional participant feedback were documented on data collection forms. Univariate statistical analysis was conducted for participant performance at critical tasks and responses to critical knowledge questions. Qualitative thematic analysis was conducted using observation data and participant feedback to identify emergent topics and themes.

7.1. Performance Tasks

The following table contains a summary of the performance tasks and the results.

7.1.1. Scenario #1: Proper Donning

Task	Task Statement	Correct Results
1	Donning of the ClearMask	18/19

7.1.2. Scenario #2: Speaking with ClearMask

Task	Task Statement	Correct Results
2	Speaking with the ClearMask	16/19

7.1.3. Scenario #3: Removal of ClearMask

Task	Task Statement	Correct Results
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3	Removal of ClearMask	19/19
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7.2. Evaluation of Performance Tasks Observations

This section is an evaluation of performance observations indicated as incorrect the test conductor.

7.2.1. Task 1

7.2.1.1. Task 1 Overview

Task number:	1
Task type	Performance/Simulation
Task	Donning of the ClearMask
Pre-Defined Correct Use	<p>Donning the ClearMask correctly with a pre-set amount of time and with a limited number of attempts:</p> <ul style="list-style-type: none"> Being able to don the ClearMask Donning the ClearMask in the correct orientation Donning of ClearMask securely with a proper fit to user’s face (no gaps)
Performance observations scored as correct	18
Performance observations scored as incorrect	1

7.2.1.2. Task 1 Discussion

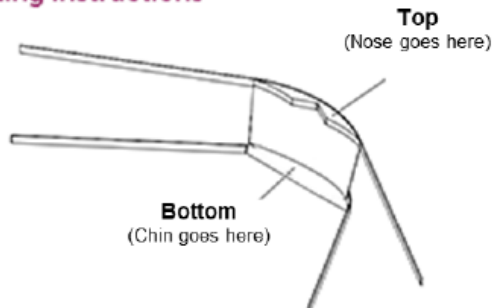
The one participant (Participant ID# 9)] donned the ClearMask on without tightening the straps sufficiently, creating a gap between the ClearMask and the participant’s face. The participant mentioned that they typically don surgical masks loosely in general.

ClearMask has clear instructions, warnings, and accompanying pictures in the Instructions for Use and on the product packaging to address this issue.

The instructional language and images represented in the labeling of the ClearMask are presented below:


The instructions and image below are printed on the packaging of the ClearMask

Fitting Instructions



1. Orient the mask so the foam faces inward toward the user, and the foam piece with the nose cutout is on the top.
2. Tie top and bottom straps **tightly and securely** around the back of the head to prevent gaps between the foam and face from forming
3. Adjust mask as needed to ensure proper fit and direct contact between the face and the foam pieces without gaps.

Scan for complete user instructions



The instructions and image below are available on page 8 of the IFU of the ClearMask

Step 6

Ensure that the mask fits comfortably and that there is direct contact between the face and the nose and chin foam pieces with no gaps



7.2.1.3. Task 1 Conclusion

There is no evidence from the human factors testing to support a need to modify the device with respect to this task.

7.2.2. Task 2

7.2.2.1. Task 2 Overview

Task number:	2
Task type	Performance/Simulation
Task	Speaking with the ClearMask
Pre-Defined Correct Use	<ul style="list-style-type: none"> • Speaking without the ClearMask shifting • Comfortable speaking with ClearMask
Performance observations scored as correct	16
Performance observations scored as incorrect	3

7.2.2.2. Task 2 Discussion

All three participants (participant ID# 7, 9, 11) were able to speak with the ClearMask shifting slightly while speaking, but not enough to impact speech or cause any gaps to form between the ClearMask and the participants' faces.

All three participants reported that it was comfortable speaking with the ClearMask, despite the ClearMask shifting slightly while speaking.

Additionally, participants number 7 and 11 reported that they felt that the ClearMask fit securely. Participant #9 was the same participant that failed to properly tie the ClearMask as described in the Task 1 Discussion above.

7.2.2.3. Task 2 Conclusion

There is no evidence from the human factors testing to support a need to modify the device with respect to this task.

7.2.3. Task 3

7.2.3.1. Task 3 Overview

Task number:	3
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Task type	Performance/Simulation
Task	Removal of the ClearMask
Pre-Defined Correct Use	<ul style="list-style-type: none"> no difficulty removing ClearMask
Performance observations scored as correct	19
Performance observations scored as incorrect	19

7.2.3.2. Task 3 Discussion

The observation notes as well as user feedback suggested that all participants were able to remove the ClearMask with no difficulty.

7.2.3.3. Task 3 Conclusion

There is no evidence from the human factors testing to support a need to modify the device with respect to this task.

8. Conclusion

Analysis of human factors/usability validation test data reveals no indication of user interface design flaws or labeling inadequacies that would prevent intended users from using the Device safely and effectively.

With respect to residual use-related risks, there is also no indication of any ongoing problem with safe and effective use that would require further mitigation or modification of the existing user interface and/or device design. Therefore, we conclude that the ClearMask is safe and effective for its intended users, uses, and use environments.