



TEST REPORT

BARDA MASK INNOVATION CHALLENGE

Round 4: The “Final Mask Face-Off”

Background and Use of Results: This testing was performed by the NIOSH NPPTL Research Branch as part of the BARDA Mask Innovation Challenge. This report does not represent endorsement by the U.S. Government or any of the agencies involved- BARDA, NIOSH, and NIST. This report may not be used in any way to imply endorsement or approval of any mask tested or the testing equipment used.

Report Date: 11/7/22

Prepared For: Global Safety First, LLC

Mask Model: ReadiMask 365

Tests Performed By: NIOSH NPPTL Research Branch, Pittsburgh, PA

Data Included In This Report:

- 1) Filtration Efficiency and Pressure Drop Testing
- 2) Static advanced headform testing (leakage ratio testing [mask fit])
- 3) Sweating thermal manikin testing (simulated thermal comfort during moderate intensity walking)

I. Filtration Efficiency and Pressure Drop Testing

Test Date: September 14, 2022

Test Description: Filtration efficiency and pressure drop using NaCl aerosol. An initial data point was collected for each replicate test on each of three mask samples.

Test Equipment: TSI, Inc. Certitest® Automated Filter Tester (model 8130A)

Sample Preparation and Mounting: Prior to testing, samples were preconditioned in an incubator for 24 hours at 85 ±5% relative humidity and 38 ±2.5 °C. For 8130A machine testing, the periphery of the mask face seal area was completely sealed to a test fixture supplied by the manufacturer. The mask is manufactured with its own adhesive face seal. No additional adhesive was applied to the mask or test fixture.

Observations and Comments: None.

Results

Table 1. Raw Data- Filtration Efficiency and Pressure Drop

Mask Sample No.	Replicate Test No.**	Flow Rate (Lpm)	Pressure Drop (mm H ₂ O)	Penetration (%)	Filtration Efficiency (%)
1	1	84.8	7.59	1.12016	98.87984
	2	85.0	8.04	1.34708	98.65292
	3	85.0	8.47	1.30256	98.69744
	4*	42.6	4.54	1.66349	98.33651
2	1	85.2	7.02	1.15945	98.84055
	2	85.2	7.31	1.33337	98.66663
	3	85.2	7.76	1.46322	98.53678
	4*	42.6	3.89	1.46766	98.53234
3	1	85.4	6.95	1.14984	98.85016
	2	85.2	7.27	1.39340	98.60660
	3	85.2	7.57	1.47823	98.52177
	4*	42.6	3.64	1.42184	98.57816

*Data at 42.5 Lpm are for informational purposes only and these data are not used for judging.

**Replicate means a repeated test on the same physical mask sample.

Table 2. Summary Statistics- Filtration Efficiency (%)

Flow Rate (Lpm)	n (tests)	Mean	Std. Dev.	Median	Min.	Max.
85	9	98.69	0.13	98.67	98.52	98.88
42.5*	3	98.48	0.13	98.53	98.34	98.58

*Data at 42.5 Lpm are for informational purposes only and these data are not used for judging.

Table 3. Summary Statistics- Pressure Drop (mm H₂O)

Flow Rate (Lpm)	n (tests)	Mean	Std. Dev.	Median	Min.	Max.
85	9	7.55	0.49	7.57	6.95	8.47
42.5*	3	4.02	0.46	3.89	3.64	4.54

*Data at 42.5 Lpm are for informational purposes only and these data are not used for judging.

Laboratory Test Photos





II. Static advanced headform testing (leakage ratio testing [mask fit])

Test Date: 10/20/22

Test Description: This test is an evaluation of mask fit utilizing static advanced headforms in various sizes. Prior to testing, the ambient room was supplemented with a 2% NaCl aerosol to achieve a total particle concentration with a minimum of 3,000 particles per cubic centimeter. Each sample underwent a single 2-min and 10-seconds breathing exercise with simulated cyclic breathing conditions of 23 Lpm (1-liter tidal volume at 23 breaths/min) produced by a breathing simulator. A TSI, Inc. PortaCount+ (model 8038) was used with the “N-95 mode” turned off. Three different headform sizes were selected for testing each sample. A single data point (overall Fit Factor) was recorded for each mask sample/headform size combination. Prior to performing the official leakage ratio test, each sample underwent an adjustment phase utilizing the “Real-Time Fit Factor” mode to obtain the best possible fit.

Test Equipment: TSI, Inc. PortaCount+ Respirator Fit Tester (model 8038); Hans Rudolf, Inc. Breathing Simulator (model 1101); i-bodi, Ltd. Static advanced headforms.

Sample Preparation and Mounting: Masks were first placed on each of the five headforms to choose three headforms for evaluation based on visual observation of gaps and the appearance of an appropriate fit. The probed mask was connected to the PortaCount with tubing.

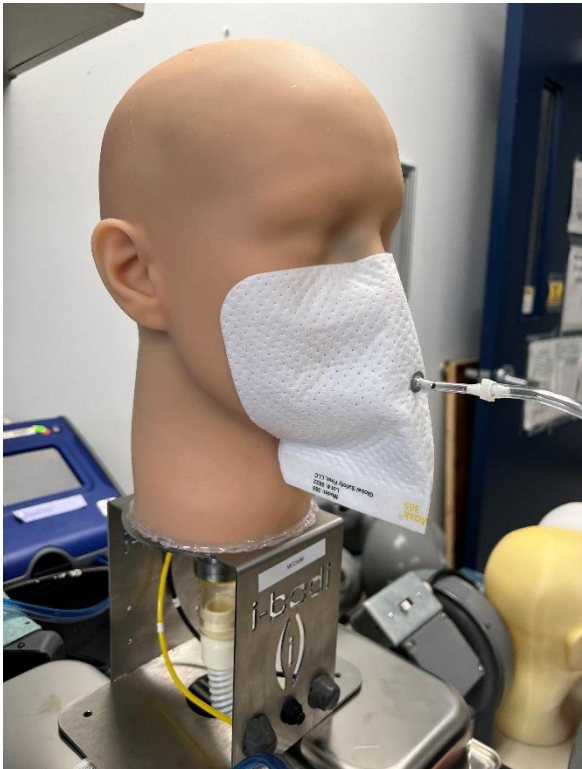
Observations and Comments: The adhesive faceseal had trouble sticking to the chin area of the static advanced headforms.

Results

Table 4. Raw Data- Leakage Ratio (Mask Fit)

Manikin Size	Mask Sample	Overall FF
Medium	1	7
Medium	2	12
Large	1	7
Large	2	10
Long/Narrow	1	8
Long/Narrow	2	8

Laboratory Test Photos



III. Sweating thermal manikin testing (simulated thermal comfort during moderate intensity walking)

Test Dates: 10/18/22 and 10/27/22

Test Description: This test was used to evaluate simulated human thermal responses to wearing each prototype. It was designed to simulate the human thermoregulatory responses to real time environmental conditions and physiologic heat production via exercise.

Test Conditions:

1-hour under both thermoneutral (20C/50% relative humidity) and hot (32C/60% relative humidity)

Manikin activity level: simulated walking exercise at 3 metabolic equivalents (METs) which is at the low end of moderate intensity.

The manikin was dressed in a standardized outfit of hospital scrub bottoms, t-shirt, and running shoes throughout all testing.

Measured Variables:

Skin Temperature (T_{sk}), Sweat Rate (S_{wa}), Heat Sensation, and Thermal Comfort specific to the whole body, face, and head separately.

Core Body Temperature (T_{hy})

Moisture Retention - prototype was measured pre/post testing for change in weight. (hot condition)

Intersegmental facial skin temperature using external thermocouples located on the forehead, nose, cheek, cheek bone, upper lip, and chin to examine differences in temperature across the face. (Informational only, not used for judging)

Variables used for judging:

Test Condition: 32C 60% RH – one hour test at 3 METS

Average Face Temperature, Face Comfort, Face Sensation, Average Body Sweat Rate, and Moisture Retention.

Test Equipment: Newton Thermal Manikin, Thermetrics, USA, Russells Environmental Chamber, USA

Sample Preparation and Mounting: Masks were donned per mask instructions.

Table 1 – Newtown Thermal Manikin (highlighted variables used in judging)

TEST RESULTS											
	Face	Head	Face	Head	Body Average	Face	Head	Body Average	Body Average	Body Average	Body Average
	Average Surface Temp	Average Surface Temp	Comfort	Comfort	Comfort	Sensation	Sensation	Sensation	Tsk	Thy	Body Average Swa
	DegC	DegC							DegC	DegC	g/min
20C 50% RH	32.37	32.64	-1.21	-1.21	-1.67	-2.37	-2.37	-1.57	32.72	37.31	1.78
32C 60% RH	35.66	35.65	-1.21	-1.21	-2.45	1.94	1.94	2.07	35.48	37.52	8.37

Tsk – Skin Temperature

Thy – Core Temperature

Swa – Sweat Rate

Comfort Scale:

4 very comfortable

just above zero - just comfortable

just below zero - just uncomfortable

-4 very uncomfortable

Sensation Scale:

4 - very hot

3 - hot

2 - warm

1 - slightly warm

-1 - slightly cool

-2 - cool

-3 - cold

-4 - very cold

Table 2: Moisture Retention of Finalist Submission vs Cloth Mask, N95, and Surgical Mask

Moisture Retention	
32C 60% RH Readimask	0.81
Cloth Mask	4.36
N95 - cup	2.10
Surgical Mask	0.66

Value reported in grams (g)

Table 3: Skin Temperatures – External Thermocouples

TEST RESULTS						
	SKIN TEMPERATURES - EXTERNAL					
	AVG TEMP					
	FOREHEAD	NOSE	CHEEK BONE	UPPER LIP	CHEEK	CHIN
20C 50% RH	29.47	31.57	30.61	32.43	31.72	31.43
32C 60% RH	34.76	36.17	34.24	36.12	34.99	35.25

Values reported in Degrees Celcius (C)



Table 4: Comparison of Finalist’s Submission* vs Cloth Mask, N95, and Surgical Mask

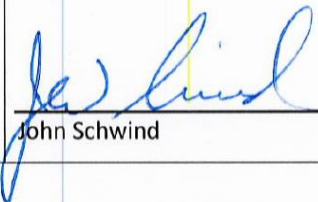
TEST RESULTS											
	SKIN TEMPERATURES - EXTERNAL										
	AVG TEMP										
	FOREHEAD	NOSE	CHEEK BONE	UPPER LIP	CHEEK	CHIN					
32C 60% RH	34.76	36.17	34.24	36.12	34.99	35.25					
Cloth Mask	34.93	36.02	33.08	36.02	32.41	34.50					
N95 - cup	34.41	36.01	34.67	35.86	33.22	35.51					
Surgical Mask	33.92	35.84	34.75	35.60	33.31	34.06					
TEST RESULTS	MANIKIN										
	Face	Head	Face	Head	Body Average	Face	Head	Body Average	Body Av	Body Average	Body Aver
	Temp	Temp	Comfort	Comfort	Comfort	Sensation	Sensation	Sensation	Tsk	Thy	Swa
	degC	degC							DegC	DegC	g/min
32C 60% RH	35.66	35.65	-1.21	-1.21	-2.45	1.94	1.94	2.07	35.48	37.52	8.37
Cloth Mask	35.66	35.88	-1.14	-1.14	-2.31	1.92	1.92	1.81	35.50	37.54	8.31
N95 - cup	35.56	35.72	-1.00	-1.00	-2.30	1.61	1.61	1.83	35.52	37.52	8.30
Surgical Mask	35.42	35.55	-1.01	-1.01	-2.41	1.44	1.44	1.61	35.30	37.49	7.65

*finalist’s submission are rows labeled “32C 60% RH”.

Laboratory Test Photos



SHIPPING FORM

SHIPMENT OF PROTOTYPE SAMPLES FOR TESTING BY NIOSH	
Ship To: Mike Bergman NIOSH NPPTL Bruceston Research Center 626 Cochrans Mill Road Bldg 13, Rm 201 Pittsburgh, PA 15236 412-386-4815 mbergman@cdc.gov	
Send all NIOSH samples for the three NIOSH tests together in the same box (minimum of 7 samples). See Table 1 for sample requirements needed for the NIOSH tests.	
Sender Name and Contact Information	Name: John Schwind Company: Global Safety First, LLC Phone: 732-616-6781 Email: JSchwind@ReadiMask.com Address: 545 Washington Blvd Suite 2 Sea Girt, NJ 08750
Product Name	ReadiMask 365
Number of Samples in this Shipment	9 – Prototype 365 respirators for testing (2 extra) 1 - Box and assembly for testing on the 8130 (previously shipped)
Number of Boxes in this Shipment	1
Comments or Concerns	
Would you like your samples returned? If so, please provide your acct. no. for either FedEx, UPS, or DHL.	Circle: Yes for box and assembly. No for samples Please use original box and previously enclosed return label for UPS shipping.
I certify that all samples are new and have not been previously worn or exposed to any pathogenic microorganisms of hazardous chemicals.	Sign and date  John Schwind Date <u>8/30/22</u>