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Characterizing Fit Factor of a One Size Fits-Most Emergency Mask using Subjects with Smaller Neck Circumferences

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The Emergency Mask (EM) is an integral part of fire response on the International Space Station (ISS), Orion, and Gateway. The EM is a hood protection respirator sealing around the subject's neck, with an additional nosecup covering the subject's oral/nasal region. When integrated with a pair of air-purifying cartridges, the system can provide safe breathing air in a post-fire environment. Initially, the EM was certified as a one-size-fits-most respirator; however, a recent requirements scrub discovered that the initial requirement set did not include the neck circumferences of the smallest possible crew population. To investigate whether the requirements gap would pose a problem for the current EM design the project performed fit tests on eight subjects with neck circumferences smaller than the initial EM requirement. The test included subjects donning an EM and performing head movements in a tent filled with approximately 50,000 particles/cc of smoke particles. During these motions, particulate measurements are obtained from within the EM and compared with particulate measurements in the surrounding environment. This paper provides descriptions of the test hardware, methodology, and results, which have provided the rationale for designing and building an EM to accommodate subjects with smaller necks.

Nomenclature

ANSUR	=	Anthropometric Survey of US Army Personnel
CAESAR	=	Civilian American and European Surface Anthropometry Resource
CBA	=	Contingency Breathing Apparatus
CDC	=	Center for Disease Control
EM	=	Emergency Mask
EM-S	=	Emergency Mask – Small
FOS	=	Factor of Safety
IRB	=	Institutional Review Board
ISS	=	International Space Station
JSC	=	Johnson Space Center
NASA	=	National Aeronautics and Space Administration
NHANES	=	National Health and Nutrition Examination Survey
OSHA	=	Occupational Safety and Health Administration
QLFT	=	Qualitative Fit Test

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QNFT	=	Quantitative Fit Test
SMAC	=	Spacecraft Maximum Allowable Concentrations

I. Introduction

THE Emergency Mask (EM) respirator is designed to be used in spacecraft emergency scenarios and has been in service since 2013 on the International Space Station (ISS) with plans to utilize on future vehicles (Orion, Gateway). Initial EM design covered an anthropometric range of *one-size-fits-most* based on International Space Station Flight Crew Integration Standard (NASA-STD-3000/T [1], also identified as SSP 50005) which encompassed 5th percentile Japanese Female to 95th percentile American Male. During the Orion flight certification process a clerical error in the published anthropometric' s minimum neck circumference was found. The original 5th percentile Japanese female neck circumference requirement was 13.6 inches; however the actual value is closer to 11 inches. After this discovery a series of tests were executed, with astronauts whose neck circumference fell significantly below 13.6 inches, along with several engineering test subjects, to determine if the current EM provides adequate protection for individuals with neck circumferences below the original incorrect anthropometric range.

II. Anthropometric Sizing Background

A. One-size-fits-most Anthropometrics

Raw data extracted from the 1988 active duty *Anthropometric Survey of US Army Personnel* (ANSUR) [2] is the basis of the National Aeronautics and Space Administration (NASA) flight crew interface guidelines for ISS. Additionally, an algorithm updated measurements to the anticipated population of 2000. Crew interface hardware designs inside the ISS accommodate body size dimensions ranging from a 95th percentile 40-year-old American male to a 5th percentile 40-year-old Japanese female.

The U.S. army re-examined original ANSUR data in a 1995 study of demographic change within the active duty army. The 1995 survey showed shifts in gender, age distributions, and racial/ethnic composition. However, none of these variables exceeded measurement error proportions [3]. As a result, the astronaut corps, seeking to minimize the impact on future crew selection, updated the population range in 2004 to the 1st percentile female to the 99th percentile male and limiting the age range to between 30-51 years of age [4].

Orion crew interface hardware designs follow the program anthropometry databook [5]. Orion's anthropometric raw data also comes from the original ANSUR data and accounts for the expected small growth in size by using an algorithm to update measurements to the anticipated population of 2015. Orion anthropometrics align with the 2004 astronaut corp updated population range of the 1st percentile female to the 99th percentile male range of age 30-51. ISS and Orion hardware designs consider dimensions in gravity conditions (1-G), with some dimensions anticipated to change in microgravity. For example, crew stature will increase by about 3% (standing) to 6% (seated) within the first 3-4 days on-orbit [6].

A U.S. Army pilot anthropometric study in 2006 showed increased body size and variability. Concerns that army personnel were no longer represented, in 2012, a new anthropometric survey was released internally (ANSUR II) integrating active, guard, and reserve forces as part of a total army concept. Some original ANSUR dimensions were redefined out of necessity in ANSUR II due to changes in human physique over time [7]. The human factor industry commonly uses other published data sets like the National Health and Nutrition Examination Survey (NHANES), which is updated every two years by the Centers for Disease Control (CDC) [8]. Another standard data set is the U.S. Air Force Civilian American and European Surface Anthropometry Resource (CAESAR), a broad 2002 survey including men and women aged 18-65 [9]. Current and ongoing human factors analysis and investigations may find additional insight within the NASA database of current astronaut anthropometry [10].

III. Test Plan Overview

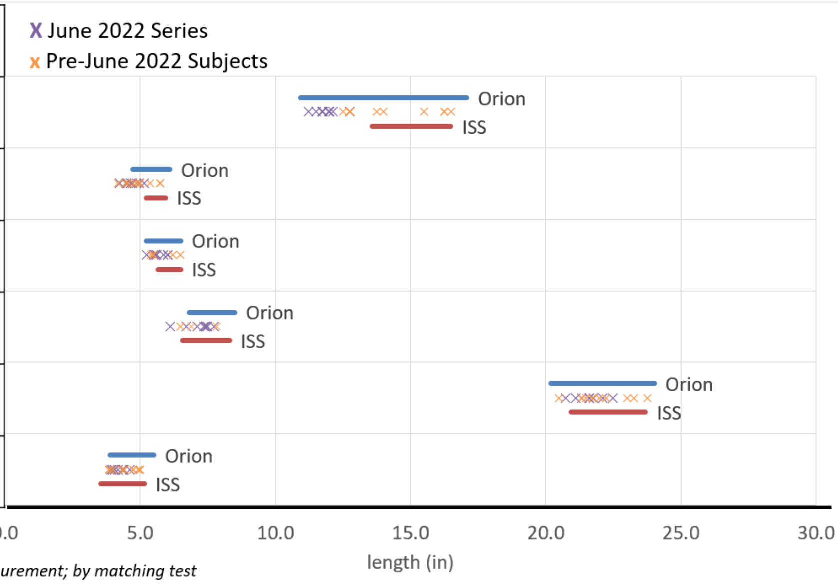
Test subjects invited to participate in this June 2022 test series have neck circumferences less than the originally tested 13.6 inches. Eight subjects with neck circumferences between 11.2 and 12.8 inches represented this study's anthropometric range. The following factors were used in selecting subjects:

- The subject with the largest neck circumference of the set, 12.8 inches, was a subject that previously had had a successful fit factor test as part of EM surveillance testing. This served as validation that the mask, procedures, and set up in June 2022 were performing as expected for this test series.
- The crew office provided the four active crew members with the smallest neck circumferences

- The remaining subjects were chosen targeting gaps in neck circumference between the five mentioned above, in addition to evaluating the capabilities of the mask with the smallest available subject (11.2 inches).

Figure 1 is a graphical representation of all anthropometric measurements previously tested within the ISS and Orion programs. While Figure 1 presents six measurements collected during testing at NASA Johnson Space Center (JSC), this paper focuses solely on neck circumference.

	Orion (in)	ISS (in)
Neck Circum.	10.9 – 17.1	13.6 – 16.5
Face Breadth	4.7 – 6.1	5.2 – 5.9
Head Breadth*	5.2 – 6.5	5.7 – 6.5
Head Length*	6.8 – 8.5	6.6 – 8.3
Head Circum.	20.2 – 24.0	20.9 – 23.7
Face Length	3.9 – 5.5	3.5 – 5.2



** ISS Test procedure does not record this measurement; by matching test subjects up to screening data was able to populate data for ~ 50% of tests*

Figure 1. A Subset of Orion and ISS Head Anthropometric Ranges.

A. Modified Fit Test

Occupational Safety and Health Administration (OSHA) lays out guidelines for use of respirators for protections in 29CFR-1910.134, *Occupational Safety and Health Standards, Personal Protective Equipment, Respiratory Protection* [11]. These guidelines include two methods to determine respirator fit: a quantitative fit test (QNFT) and a qualitative fit test (QLFT) As their names imply, the QNFT method provides a quantitative result (numerical fit factor), while the QLFT provides a qualitative result (questionnaires or observations).

NASA primarily utilizes the QNFT process documented in OSHA 29CFR-1910.134, Appendix A. The QNFT test is geared towards respirators where assumes the primary seal is the nose cup to the face; the Emergency Mask actually has two seal, one at the nose cup and one at the neck dam with the neck dam being the primary seal. Therefore it is necessary to modify the test set up to move the sample point from inside the nose cup to inside the hood to evaluate the neck dam seal as show in in Figure 2. Besides sample location, the other notable deviation is the type of contaminate used in the test. The OSHA standard recommends non-hazardous test aerosol like corn oil, polyethylene glycol 400 [PEG 400], di-2-ethyl hexyl sebacate [DEHS], or sodium chloride. It is recognized that these alternative, simulated contaminants represent a potential improvement; tea candle smoke was employed as the simulated contaminant in order to expedite testing using readily available hardware and instrumentation as well as

Figure 2. Sampling tube breaching the nosecup and adhered to the inside of the hood.

maintain consistency with prior historical testing of this respirator. The majority of the procedure in terms of creating the environment, donning the EM, executing the test, and data analysis are in line with the OSHA standard. A deviation was introduced for one subject during the June 2022 test which will be discussed further in the discussion.

The test area used in this study was an enclosed environment filled with smoke particles. Prior to the test the EM is configured with two respirator cartridges, a QNFT sampling adapter and the pass through tube described in Figure 2. At the start of the test the test subject dons the EM and performs a purge protocol [12] outside the smoke filled environment. The EM is then connected via the sampling tube to a particle-counting device; the test subject breathes normally to purge particles trapped inside the mask. Simultaneously, inside the test area, a test conductor establishes a particle environment of >50,000 particles/cc.

Once the particle level inside the mask is suitably low (goal is <10 particles/cc) and the test environment is >50,000 particles/cc the subjects enters the smoke-filled environment. After a brief pause to verify the test environment is still at >50,000 particles/cc a series of eight exercise is completed. All exercises, with the exception of grimace, are performed for 60 seconds. The OSHA standard recommends 15 seconds for grimace but the particle counter recommends 40 seconds; NASA currently uses the 40 second option.

1. Normal breathing with head motionless
2. Deep breathing with head motionless
3. Turning head slowly from side to side while breathing, pausing for at least two breaths before changing direction
4. Moving head up and down while breathing, pausing for at least two breaths before changing direction
5. Talking out loud while breathing normally; the subject may count backward from 100, read the Rainbow Passage, or recite a memorized poem or song
6. Grimace intentionally creates a leak in the mask face seal by smiling or frowning and allowing it to reseat before the next exercise
   Note: Grimace often results in a failed exercise and is usually excluded from the overall fit factor calculation. However, grimace can change neck shape and as discussed in section VI this is an area of particular sensitivity for the EM. Therefore, grimace in the overall fit factor calculation.
7. Bend at the waist to touch toes or jog in place while breathing normally
8. Normal breathing

Post QNFT test, the test subject exits the smoke-filled environment and doffs the respirator. The particle counter software calculates a numerical fit factor for each of the eight exercises and computes a weighted average into the overall fit factor. Lastly, the test team performs the QLFT test where the test subject answers a questionnaire about EM functionality. e.g., mask fit, visor visibility, and other test oddities.

B. How to Calculate Fit Factor

A fit factor is one of the essential criteria when describing the performance of a respirator. OSHA associates the level of risk involved with each event requiring a respirator with the level of protection a respirator provides against contaminants. Based on OSHA guidelines, NASA assigned a minimum fit factor (also referred to as protection factor) of 500 against the EM in the JSC-47326 Rev B, *Project Technical Requirements Specification (PTRS) for the Emergency Mask System* [13]. This fit factor of 500 was carried forward to Orion and Gateway programs though, as documented in the discussion below, Orion was able to lower the fit factor requirement to 100 based on the specific fire scenario.

During a fit test the particles inside and outside the respirator mask are measured. To calculate fit factor, the particle levels before and after the test outside the respirator are averaged and divided it by the particle concentration inside the mask for each of the eight fit test exercise resulting in FF1, FF2, ...FF8 (Eq. 1).

$$FFx = \frac{C_B + C_A}{2C_R} \tag{1}$$

FFx = fit factor of each individual exercise
C_B = particle count in ambient sample prior to respirator sample
C_A = particle count in ambient sample after respirator sample
C_R = particle count in respirator sample

Using the individual exercise fit factors a weighted average of the eight exercises is calculated to arrive at an overall FF (Eq. 2). Given the nature of this method one failing exercise may not necessarily fail the overall test score.

$$FFo = \frac{n}{\frac{1}{FF_1} + \frac{1}{FF_2} + \frac{1}{FF_3} + \cdots + \frac{1}{FF_{n-1}} + \frac{1}{FF_n}} \quad (2)$$

FFo = fit factor overall
FFx = fit factor for exercise
n = number of exercises

IV. Test Hardware

A. The Emergency Mask

The EM is a passive device made of self-extinguishing fabric and seals at the neck via a butyl rubber neck dam preventing contaminants from entering the volume within the hood. Figure 3 shows the dual standard bayonet fittings with orange gaskets that accommodate a pair of respirator cartridges. The EM is a one-size-fits-most model designed to fit crewmembers ranging from a 5th-percentile Japanese female to a 95th-percentile American male [13].

Figure 3. The Emergency Mask is a custom respirator hood built exclusively for NASA.

B. Model 8030 PortaCount® Pro

The Model 8030 PortaCount® Pro is an particle-counting device that quantitatively assesses respirator leakage. It measures the particle count of two samples and compares them, one being an environmental sample and the other sampling the respirator. A 5.5-foot twin tube is used with one leg connecting the PortaCount to the respirator and the second leg sampling the environment.

C. Test Area

Figure 4 exhibits the commercial 6x6 foot pop-up tent containing the particles generated via burning tea candles. The pop-up tent has one central zippered opening and a window on the opposite side that can be open or shut and secured via hook and loop fastener. Particulate levels are continuously monitored by the PortaCount and maintained by adjusting these openings throughout each test and lighting more or less unscented tea candles. Given the length of the PortaCount twin tube, it was necessary for the test subjects to stand just over the tea candles, negating the need for mixing.

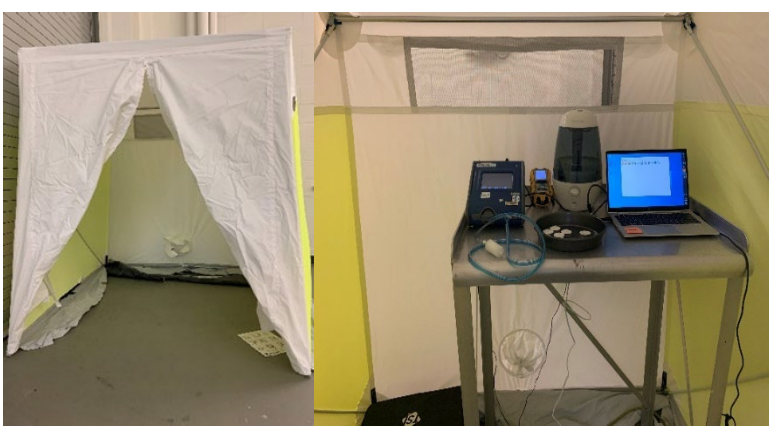


Figure 4. Pop-up tent and test equipment in tent.

D. Test Aerosol (Smoke)

Smoke particles are introduced into the test environment via a tea candle. A single tea candle typically can hold the ambient concentration steady for 30-45 minutes at >50,000 particles/cc. Between using the tent window to regulate air flow in/out and occasionally lighting a second candle when particle levels drop it is possible to maintain a >50,000 particles/cc environment. Candles were re-used from one run to another, being replaced as they burned down with on average three candles consumed for each test subject.

Figure 4 shows the configuration of the interior of this tent, along with the general placement of the PortaCount and tea candles. Note that Figure 4 displays a humidifier on the test table. The original plan included potentially using a humidifier to obtain the proper particle count in the tent; however, the humidifier was never needed (or used) in this test series.

V. Test Results

Each test run produced data for both the individual exercise and the overall fit factor. This data was processed using Eq 1 and 2.

Figure 5 shows the data report provided by the PortaCount after each test run with the fit factor for each exercise (Eq 1) displayed on the left and overall fit factor (Eq 2) displayed on the right. Some exercises, like the deep breathing exercise where the test subject clears the hood space efficiently using their lungs, understandably result in a higher score, while other exercises like head side to side which requires movement, result in lower scores.

Exercise	Fit Factor
1. NORMAL BREATHING	33221
2. DEEP BREATHING	65445
3. HEAD SIDE TO SIDE	5
4. HEAD UP AND DOWN	8
5. TALKING	53
6. GRIMACE	265
7. BENDING OVER	838
8. NORMAL BREATHING	900

Test Status
Fail: Overall Fit Factor 22

PortaCount Status
Connected

Figure 5. Screenshot of PortaCount display

Each subject completed between four and five runs, and the overall score for each run was collected and compared to the ISS requirement of 500. Figure 6 collates the neck circumferences with the overall fit factor for each test run and whether the fit factor met the requirement.

	Run				
Neck Circ (in)	1	2	3	4	5
11.2	R	G	R	R	R
11.5	R	G	G	R	G
11.7	R	R	R	R	N
11.8	R	G	G	G	N
12.0	R	G	R	G	N
12.0	R	R	R	R	N
12.1	G	R	G	R	N
12.8	G	G	G	G	G

Data Key:

Fit Factor < 500	Does Not Meet Requirement
Fit Factor > 500	Meet Requirement

Figure 6. Fit factor test summary for eight test subjects with a smaller neck circumference.

VI. Discussion

The results of the June 2022 test series generated several areas of discussion. This includes the failure to meet a fit factor of 500 at neck circumferences smaller than 12.8 inches, the fit factor trends between exercises, and the impact of neck structure on the outcome of testing.

A. Failure to meet Fit Factor of 500

Subsequent to the June 2022 ISS and Orion re-examined the emergency scenarios in which the EM would be used. A blanket fit factor of 500 has been used for the last 15 years because there were no issues with subjects meeting a fit factor of 500. OSHA and industry do allow for fit factors lower than 500 depending on the environment and level of protection needed (e.g. if the person will be in the environment for 15 minutes, then the allowable exposure can be greater than a scenario where the person will be in the environment for 8 hours).

To determine if a fit factor below 500 is acceptable, analysis was performed to compare the environment to allowable exposure. There are multiple factors in the analysis such as breathing rate, fit of the nose cup, and permeation of material but the driving factor is the ratio of the maximum concentration produced by a reference fire for Acrolein to the 24-hour Spacecraft Maximum Allowable Concentrations (SMAC) [14] levels. As shown in Figure 7 all other constituents identified require a fit factor one magnitude less than that required by Acrolein. Therefore, a fit factor of 47 became the driving factor in discussions.

	Cabin	Cartridge Effluent	
Constituent	Max Concentration (ppm)	24-hour SMAC (ppm)	*Fit Factor (minimum) to protect for 24-hour SMAC*
2-Methylpropenal	0.36	0.35	*~1*
Acetaldehyde	8.44	6.0	*~1*
Acrolein	1.7	0.035	*47*
Acrylonitrile	2.6	1.52	*~1*
Benzene	15.34	3.0	*~5*
Carbon Monoxide	588.34	100.0	*~6*
Formaldehyde	1.19	0.5	*~2*
Hydrogen Chloride	0.27	2.0	--
Hydrogen Cyanide	0.49	4.0	--
Hydrogen Fluoride	1.86	2.5	--
Methyl Nitrite	14.36	7.0	*~2*

Figure 7. Comparison between max cabin concentration, 24-hr SMAC level, and the calculated Fit Factor based on these two.

After discussing these results with the Orion community stakeholder agreement was reached to change the PTRS requirement from a fit factor of 500 to a fit factor of 100 with a goal of 500. A fit factor of 100 was based on taking the fit factor of 47 for Acrolein, apply a FOS of 2, and minor rounding. Using the revised requirement the data in Figure 6 was re-processed with these new values, roughly halving the number of instance where the requirement is not met (Figure 8).

While the new requirement did not eliminate the need for a waiver it reduced the magnitude of the issue. Working backwards from the lowest fit factor reflected in the test series, it was determined that fit factor equates to a 1-hr SMAC for Acrolein. At the 1-hr SMAC level a crew member may experience irritation (likely ocular) but toxicology does not expect the exposure to be life threatening. Therefore, Orion approved a one mission waiver to use the EM design for Artemis 2 [14].

While ISS has examined various emergency scenarios there is no requirements change for ISS at this time. Gateway is in the earlier stages of requirement development so an minimum fit factor has not been determined; however, it is anticipated that Gateway will follow Orion's lead, with the shall of 100 and a goal of 500 given the reference fire for Gateway is based on the Orion reference fire.

	Run				
Neck Circ (in)	1	2	3	4	5
11.2	O	G	R	O	Y
11.5	Y	G	G	Y	G
11.7	Y	Y	Y	Y	N
11.8	O	G	G	G	N
12.0	R	G	Y	G	N
12.0	R	R	O	Y	N
12.1	G	R	G	O	N
12.8	G	G	G	G	G

Data Key:

Fit Factor < 47	Does Not Protect For 24 hr SMAC
47 < Fit Factor < 100	Below Revised Requirement
100 < Fit Factor < 500	Meets Revised Requirement Below Original Requirement
500 < Fit Factor	Meets Revised and Original Requirement

Figure 8. Fit factor test summary with revised requirement

B. Fit Factor Trends Between Exercises

As the series was performed a trend was observed the third exercise, head side to side, was often the lowest performing test, suggesting the largest leak occurs during this exercise. The tests following head side to side followed a trend of increasing performance as the sequence proceeded. Figure 8 illustrates this with head side to side being the lowest, a slight recovery in head up and down, more recovery on talking and grimace, and finally achieving 500 with the bending over exercise. After observing this behavior on several tests the team theorized that it was not necessarily that there were leaks on head up and down, talking, and grimacing but rather the leak produced during head side to side introduced many particles in the mask that it required more than the standard 10-20 seconds of purge between measurements to remove the contaminant. The data suggested the actual time required was closer to 2-3 minutes.

To evaluate this theory a test was attempted where head side to side was moved to the end of the test series and the outcome compared to a run with the same subject in the original order (Figure 9). The difference was noticeable in that none of the exercises failed or even had a major dip in fit factor with the exception of head side to side.

	Run 1
Normal Breathing	111570
Deep Breathing	160552
Head Side to Side	6
Head Up and Down	10
Talking	55
Grimace	363
Bend Over	1760
Normal Breathing	6316
Overall FF	27

Swapped Head Side to Side with Normal Breathing to give time to not have "dirty" environment muddy following tests

	Run 3	Run 4
Normal Breathing	61041	45032
Deep Breathing	53775	75115
Normal Breathing	67855	63232
Head Up and Down	49430	42260
Talking	26280	51157
Grimace	47709	91837
Bend Over	44096	120303
Head Side to Side	10	14
Overall FF	86	113

Figure 9. Revised test order to investigate head side to side impact

While a change to the order of exercises is not planned in the future, anticipating that head side to may erroneously result in a failed fit factor may aid with troubleshooting. A shorter test focusing on head side to side to evaluate changes to the hardware or crew procedures may expedite future efforts.

C. Impact of Neck Structure on Mask Fit

Figure 10: Neck gapping

As the impact of the head side to side movement to fit factor was being assessed, the team also examined factors that may be causing the head side to side movement to result in increased leakage. An additional question geared towards the specific head side to side movement was added to the QLFT questionnaire. Some test subjects did report the feeling of gapping or even air flow as they turned their head side to side. Images and videos revealed gaps between the neck dam and skin forming during this movement. Figure 10 illustrates one such instance of the gapping occurring. In particular, it was observed that subjects with muscular necks tended to have the most severe gapping.

VII. Limitations

There are several limitations to the test method and analysis described in this paper. Some of these were known and accepted as a result of the test methodology while others were discovered over the course of executing the testing.

- Test Aerosol (Smoke) – The test methodology utilized tea candle smoke to produce particulates at levels significantly below what would be expected in an actual fire event. This limitation was employed for both test subject and test personnel safety. The levels used (in general 50,000 to 100,000 particles/cc) were low enough that the IRB was able to approve the test without special test safety controls for particulate exposure. The team is aware this test is not a true representation of a fire but instead geared specifically towards determining fit. Other tests and analysis are performed on the EM to determine the total level of protection provided from the level of particulates anticipated during an actual fire scenario. Testing also addresses permeation in the event of an 8,000 ppm Ammonia leak as the EM is also certified for use on ISS for an Ammonia Leak [15].
- 1% Female Limitation - Orion's anthropometric range is larger than ISS in that instead of 5% Japanese Female as the lower bounding case, the program is targeting 1% (generic) Female. For neck circumference, this value is 10.9 inches. During the June test, the team was unable to find a subject or crew member below 11.2 inches. As is discussed in future work below, when a second size becomes available, even if a fit factor of 100 was reached with all subjects, some level of risk acceptance and a potential waiver may be required, because the test did not reach the lower limit of the requirement, unless a subject is found at 10.9 inches neck circumference.
- Human Variability – Early theories about a relationship between performance and neck circumference (e.g. performance would improve as neck circumference increased) were disproven with this test. There were smaller subjects that over the 4-5 runs performed better than larger subjects. Three subjects of the same size (12.0 - 12.1 inches) had varying results. Even across a single subject, results could vary greatly with some passes and some failures. Neck structure, as discussed above, is one factor anticipated to contribute to fit factor. Additionally, after observing the eight subjects and analyzing the data, it was observed that significant difference exist between each don of the EM. Finally, factors such as how smoothly the neck dam laid against the neck, where it laid on the neck, whether hair or other particulates may have been present are all potentially contributing to the variability. Given that there will always be variability in a human interface, the team recognizes the need to test as well as implement a level of conservatism, such as including the FOS of 2 on the new Orion requirement.

VIII. Future Work

As a result of the identification of the erroneous neck circumference range and subsequent June 2022 Fit Factor testing and data analysis, it is not feasible for the current mask design to address the entire revised range. Consequently, a proposal was brought forward to ISS, Orion, and Gateway to pursue an additional size.

The proposal was accepted and design of a second size was initiated in November of 2022. The second, smaller size will leverage the original mask design but incorporate a smaller neck dam. Other minor changes include a different color fabric to distinguish between sizes quickly during an emergency. Finalization of the design, production, testing and certification are anticipated to complete in 2024.

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