

Fit Capability of Differing N95 Duckbill Surgical Respirators in Relation to NIOSH Standard Face Sizes and Shapes

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Purpose:

To utilize a quantitative test method to determine the fit capability of three N95 respirators. This report contains data for three different N95 respirators.

Materials:

Crosstex™ Isolator™ Duckbill Surgical N95 Respirator, ProGear® N95 Particulate Filter Respirator and Surgical Mask, and Halyard Fluidshield* 3 N95 Particulate Filter Respirator and Surgical Mask.*

Experimental Design:

Test: ASTM F3407 test protocol as recommended for an N95 respirator.

Volunteers: Volunteers were chosen from a 25 person sample and were tested with each mask and respirator using the *NIOSH Bivariate Test Panel* (*NIOSH* head forms) corresponding to 98% of the respirator wearing U.S. population.

Test Method:

The *ASTM F3407* standard is designed for testing respirator fit capability of negative-pressure half-facepiece respirators.

A *PortaCount® Pro+ Respirator Fit Tester (TSI)* was utilized for the experiment. Each of the respirators were tested for fit capability on ten different head types. Multiple digital and manual face measurements were taken and documented for each of the volunteers to determine the qualification of the test subject in the *NIOSH Bivariate Panel*. The test administrator familiarized the test subjects on the donning and doffing procedures of each respirator according to the manufacturer's user instructions. A description of each of the exercises was provided before the test began.

The Respirator Fit Capability test consists of seven, 1-minute-long exercises and one 15-second-long exercise. The first exercise is normal breathing, followed by deep breathing, head side-to-side, head up and down, talking aloud, grimacing (15sec), bending over, and finally, normal breathing.

For the standard to be met, at least 13 of the 25 test subjects must obtain an average Fit Factor result greater than 100 for the respirator model to be considered a successful pass. Fit Factor is a representation of how well the respirator seals onto the face and is determined by comparing the number of particles inside the respirator to the number of particles in the ambient air. A quantitative measurement is provided following all exercises, and each exercise provides a pass or fail threshold.



PortaCount® Pro+ Respirator Fit Tester (TSI) and screen results



Manual face measurement



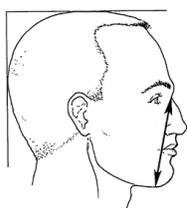
Head side-to-side exercise



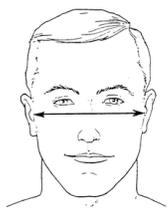
Head up and down exercise



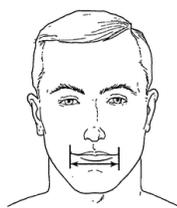
Bending over exercise



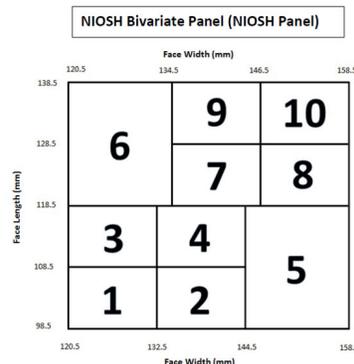
Face length measurement:
Distance as measured with a sliding caliper in the midsagittal plane between the menton landmark and the sellion landmark.



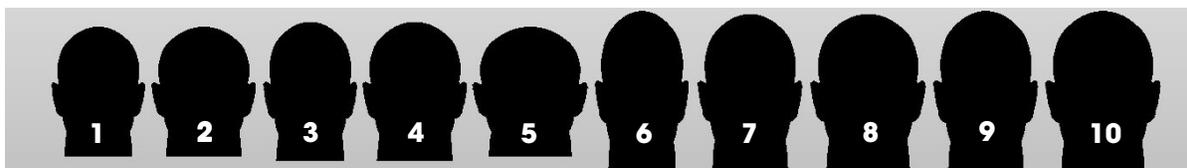
Face width measurement:
Maximum horizontal breadth of the face as measured with a spreading caliper between the zygomatic arches.



Lip length measurement:
The straight-line distance between the right and left Chelion landmarks at the corners of the closed mouth is measured with sliding caliper.



Head Sizes (Panel Sizes)



Conclusion:

The ASTM F3407 voluntary standard was conducted as written for testing the N95 respirators. The standard is designed for testing respirator fit capability of negative-pressure half-facepiece respirators. After completing 10/10 head types given in ASTM F3407 for the three N95 respirators, all three respirators tested, the *Crosstex™ Isolator™ Duckbill Surgical N95 Respirator*, *Halyard* Fluidshield* 3 N95 Particulate Filter Respirator and Surgical Mask*, and *ProGear® N95 Particulate Filter Respirator and Surgical Mask*, successfully completed the standard and met the criteria of fitting at least 50% of the faces in the *NIOSH Bivariate Panel*.

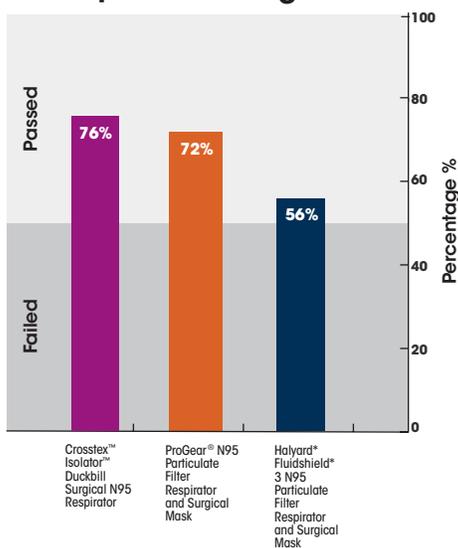
The data raise questions on what factors assist in achieving a fit factor above 100. During the testing, it was noted that placement of the straps and how well the respirator straps were able to keep the mask taught against the user’s face was also significant in achieving a passing fit factor. Both participants in Panel 2 were within 2mm in both face length and width but tested very differently. When comparing both participants in Panel 2 there was a noticeable difference in the slack present in the respirator straps. A panel that accounts for the head depth could provide more data that would allow exploration of what other factors contribute to the wearer getting and maintaining a seal.

Study limitations included a small sample size; additional participants would be an advantage for statistical significance.

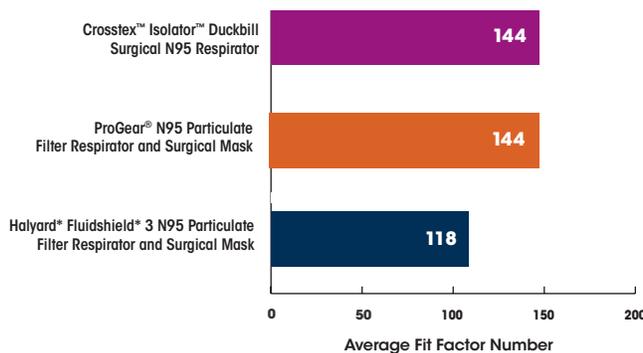
Respirator Passing Rate

50% of participants must pass to meet ASTM standard

*The actual passing rate of the respirator is based on 25 test subjects. We were unable to test a second #9 head type. The assumption was made that the excluded subject head type would fail.



Fit Capabilities of Tested Respirators



100 is considered to be a successful seal to the face

- *Crosstex™ Isolator™ Duckbill Surgical N95 Respirator* passed all but head type 10 for those subjects tested.
- *ProGear® N95 Particulate Filter Respirator and Surgical Mask* passed for a person with each head type for those subjects tested.
- *Halyard* Fluidshield* 3 N95 Particulate Filter Respirator and Surgical* passed for every head type except head type 5.