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Protection  
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Fit and Fit Testing

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Shawmut  
Corporation

West Bridgewater,  
Massachusetts  
USA

# Comparison Study of In-Market Filtering Facepiece Respirators Using ASTM F3407-20 RFC Standard to Evaluate Design and Component Impact on Overall Fit Capabilities



## The Purpose of the Study was Multi-fold:

1. To assess the ability of the ASTM F3407-20 Respirator Fit Capability Standard to compare the fit capability performance of a range of commercial NIOSH-approved disposable N95 filtering face piece respirator (FFR) designs
2. To understand how FFR design and construction factors may impact fit performance
3. To assess the relative performance of the KN95 FFR design compared to N95 FFR designs

## Scope of ASTM F3407-20 Testing Performed:

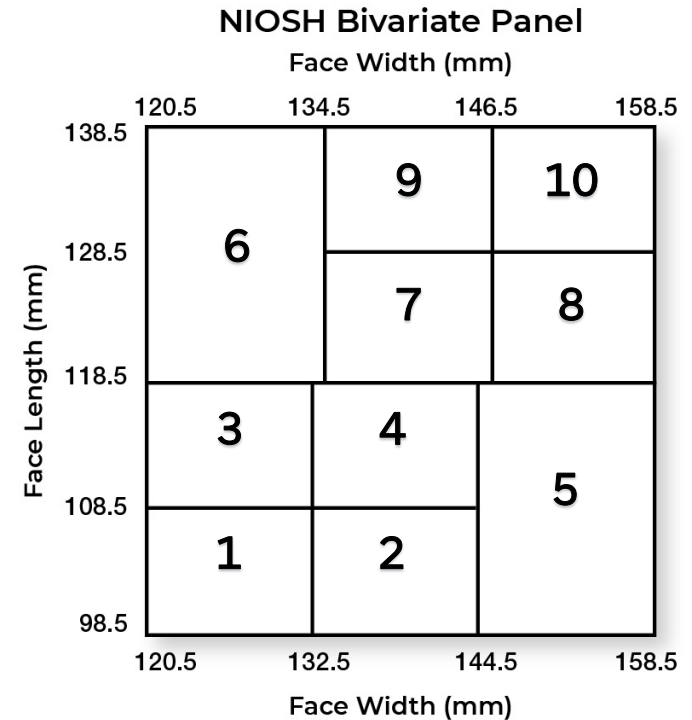
- 18 current market models were evaluated
- 12 NIOSH-approved N95 disposable respirators comprised of cup, duckbill, tri-fold and vertical flat-fold designs
- 5 KN95 models
- 1 KF94 model
- 450 individual subject tests
- 3,600 interior air samples evaluated and recorded



## Key Findings:

1. Fit performance varied dramatically across individual N95 models
2. Some form factors seem to be more robust than others
3. KN95 masks do not deliver comparable safety performance
4. Fit capability is essential to understanding respirator performance

## A NIOSH Bivariate Test Panel was Drawn from Shawmut's Workforce

- The width (zygomatic arches) and length (menton-sellion length) of the test subjects' faces were measured using the digital caliper.
- The average of the bizygomatic breadth and the menton-sellion length are identified with a panel number from the NIOSH panel.
- All test subjects were free of facial hair and other facial characteristics that would impact a proper fit. It was confirmed that all test subjects had not eaten or smoked within a half hour prior to the test.
- Each subject was instructed how to correctly don the mask to achieve a good fit. Using a TSI PortaCount Plus® Model 8048 in the N95 companion mode, each subject was tested following the OSHA 29CFR1910.134 protocol, which consists of eight exercises.
- The make up of the panel was held constant across all testing to the degree possible and was comprised of 13 males and 12 females.



Description	Definition	Diagram
<b>Bizygomatic Breadth</b>	Maximum horizontal breadth of the face as measured with a spreading caliper between the zygomatic arches.	
<b>Menton-Sellion Length</b>	Distance as measured with a sliding caliper in the midsagittal plane between the menton landmark and the sellion landmark.	

## ASTM F3407-20 Test Method of Respirator Fit Capability

All test equipment has been calibrated and is traceable to NIST standards.

- TSI PortaCount Plus® model 8048 with applicable software
- Two (2) TSI Particle Generators with NaCl solution
- Hexagon digital caliper
- NIOSH Bivariate Test Panel
- Small fan to evenly distribute particles in enclosed area

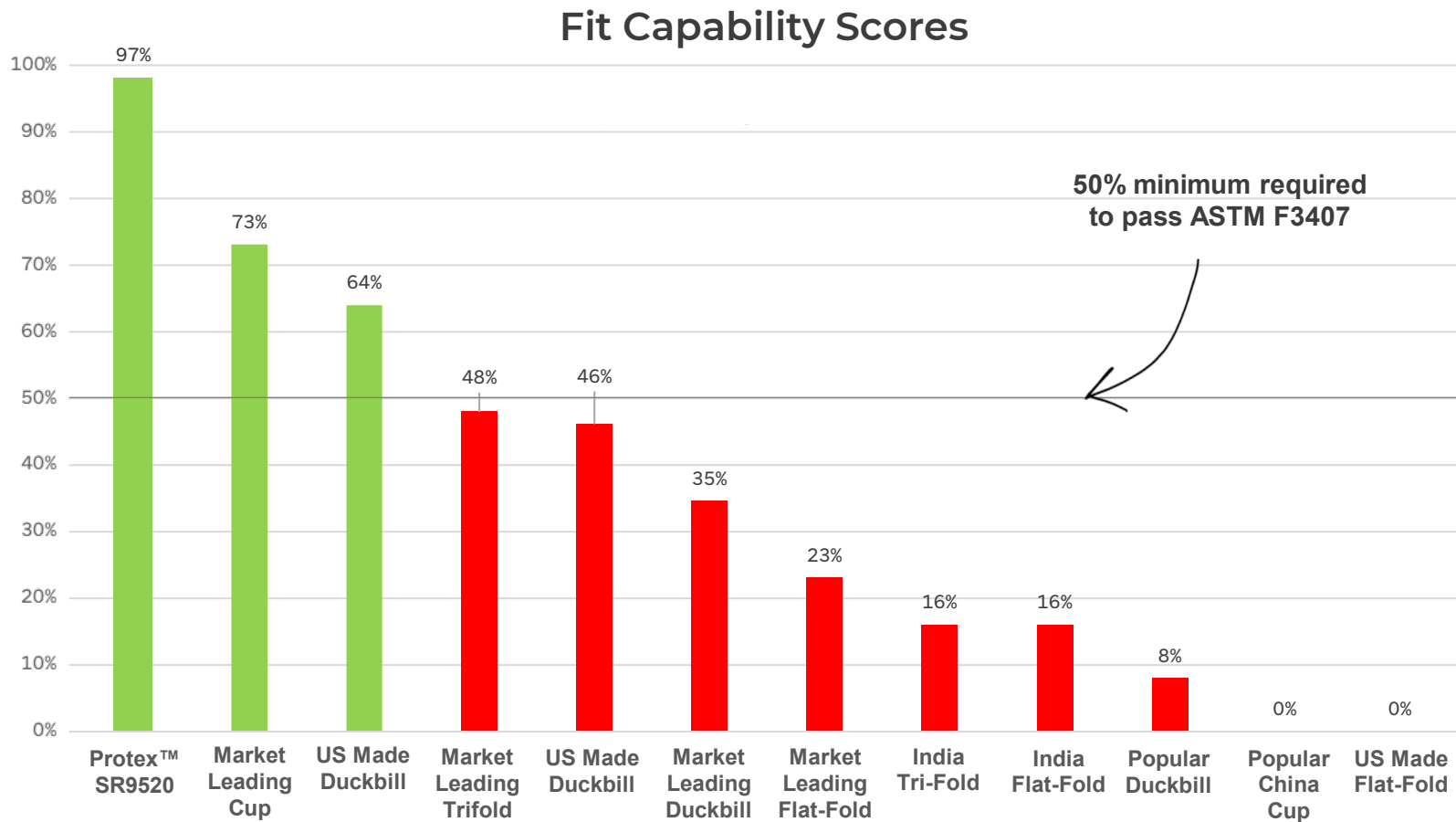


## Apparatus and Equipment

- An enclosed area is 72" x 72" x 98" and is isolated from the outside air.
- Two (2) TSI particle generators are run at the same time with a small fan to circulate and evenly distribute the particles.
- The particle count was maintained between 2000 – 8000 particles/cm<sup>3</sup> and within  $\pm 10\%$  of the initial particle count throughout the duration of the test.
- A diagnostic check was performed several times each day. This includes the chamber concentration, particle classifier check, zero check with manufacturer's HEPA filter, and the Maximum Fit Factor check.
- The facepiece is probed so that the opening is between the base of the nose and the mouth.

# NOT ALL N95S MEET THE FIT CAPABILITY STANDARD

Using the ASTM F3407-20 RFC Standard, We Tested Market Leading and Popular Models



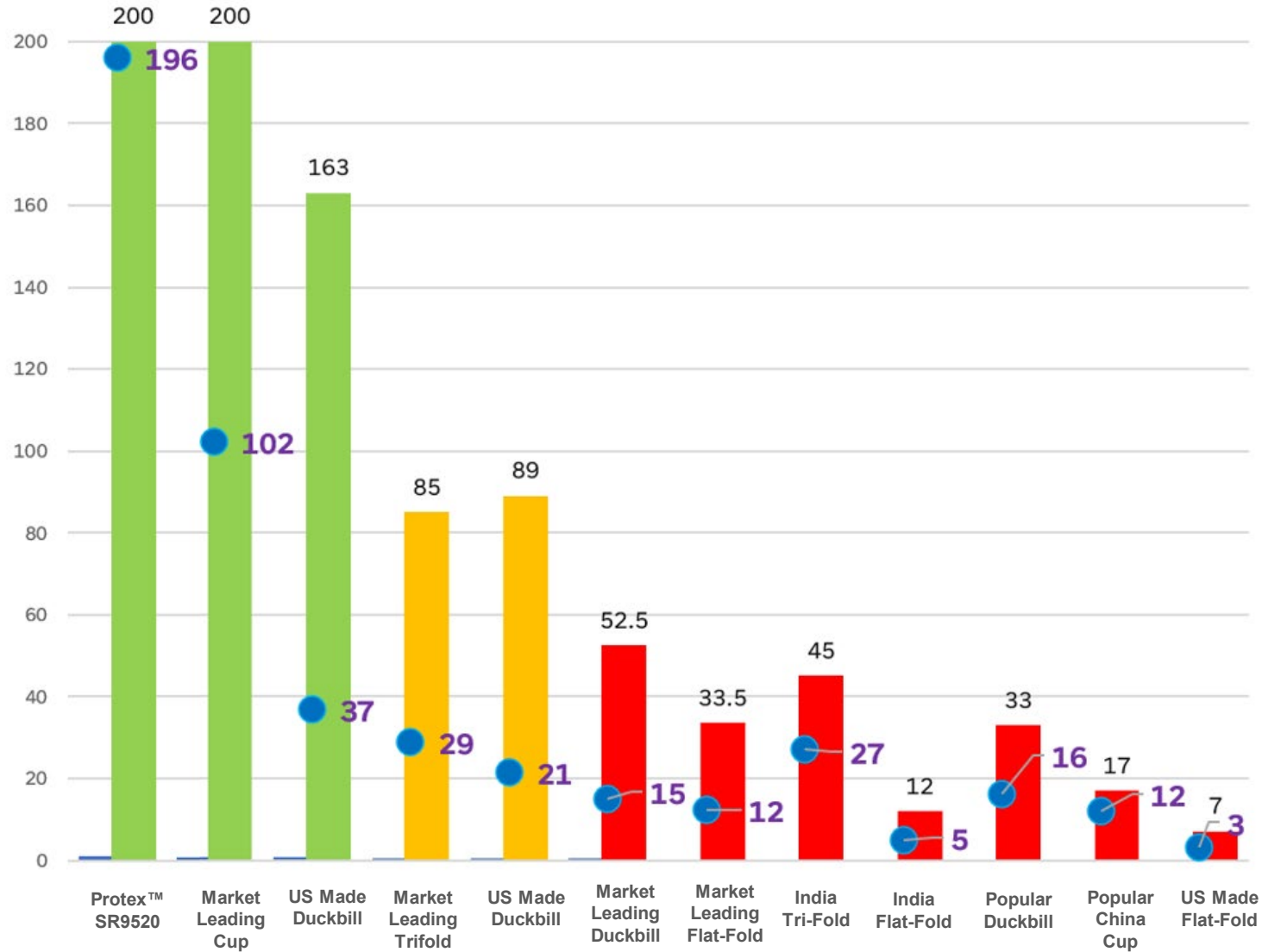
- Fit capability is essential to understanding respirator performance, but most N95s tested did not fit well
- Fit performance varies dramatically across individual N95 models
- Most N95s tested did not meet the fit capability standard which calls for a minimum fit capability of 50%

To pass, a respirator must get a passing Fit Factor score of 100 or more on more than 50% of the test subjects.



# FIT VARIABILITY FOR GENERAL CONSUMER USE

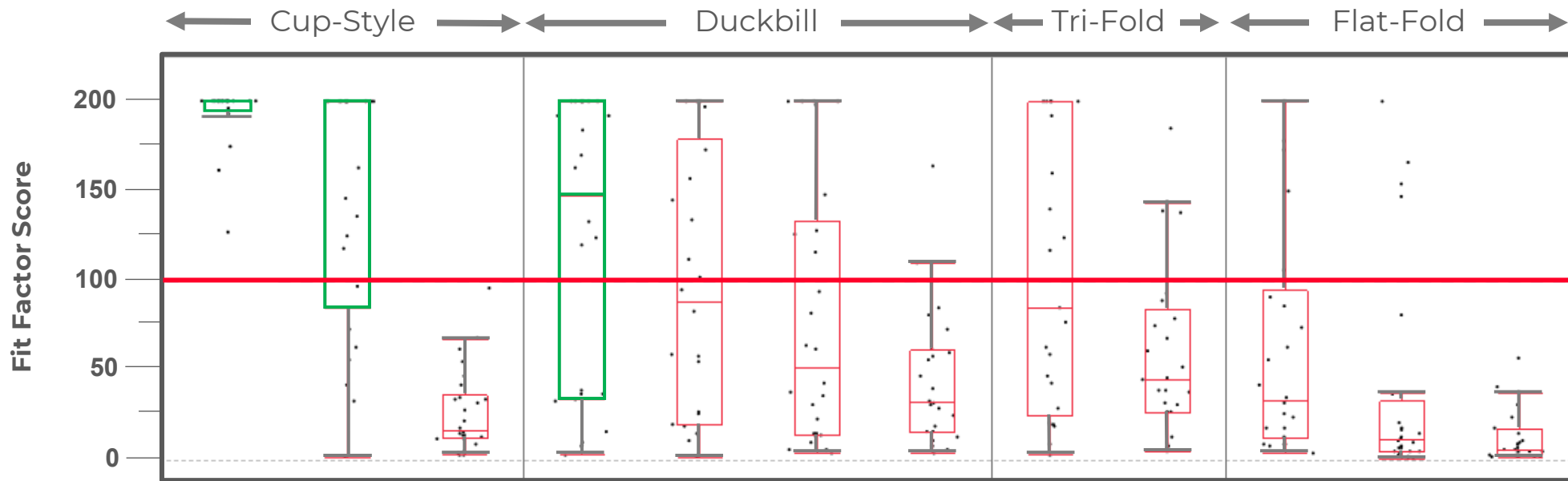
## Median and Lower Quartile Performance



- Some respirators offer more consistent fit across wearers
- Fit variability may be an important metric for general consumer use

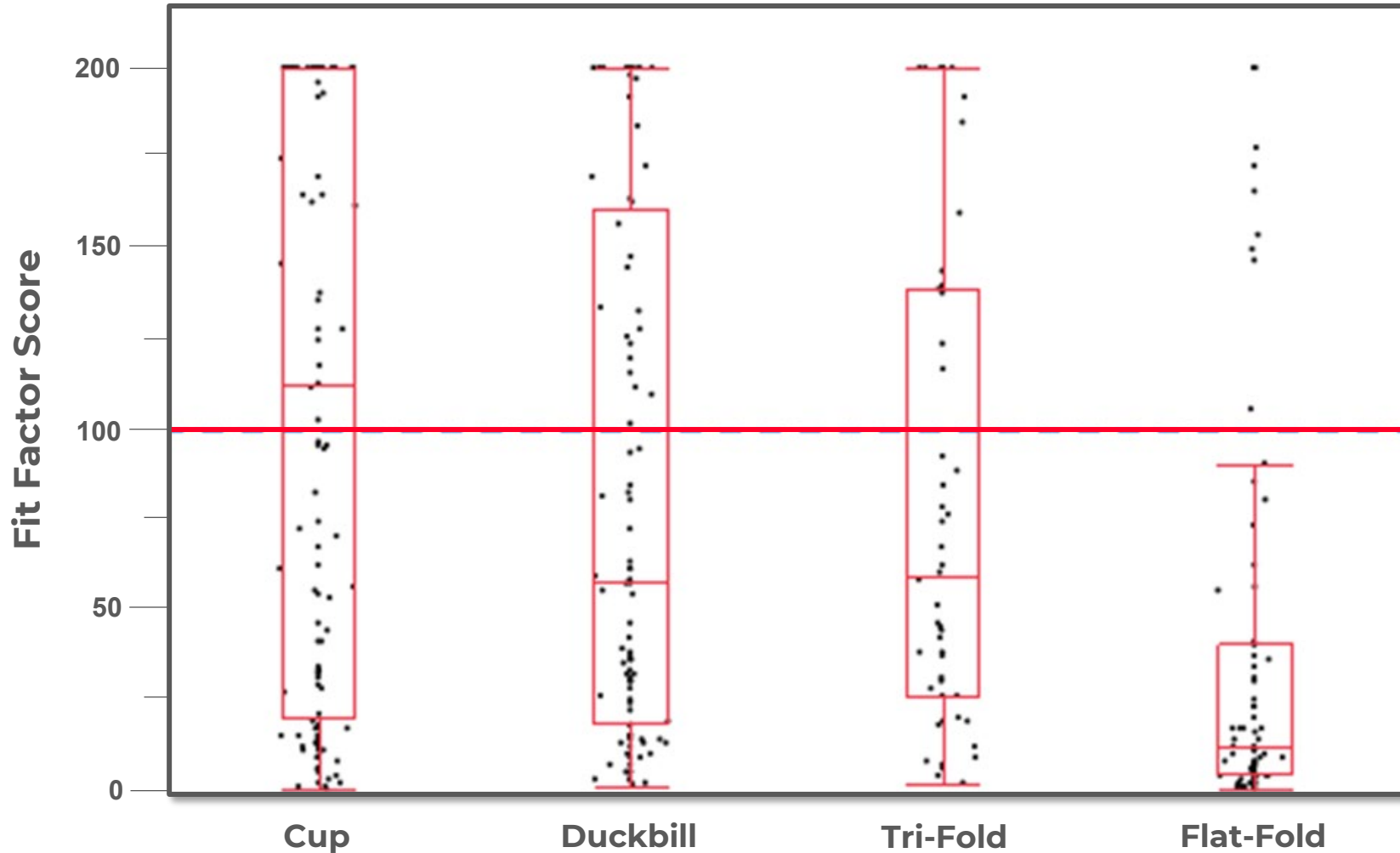
# N95 DESIGN STYLES TESTED

## Performance Variation Within Several N95 Models



Model	Protex™ SR9520	Market Leading Cup	Popular China Cup	US Made Duckbill	US Made Duckbill	Market Leading Duckbill	Popular Duckbill	Market Leading Tri-Fold	India Tri-Fold	Market Leading Flat-Fold	India Flat-Fold	US Made Flat-Fold
Pass/Fail	PASS	PASS	FAIL	PASS	FAIL	FAIL	FAIL	FAIL	FAIL	FAIL	FAIL	FAIL
# of Panelists that Pass (minimum of 13 needed)	24	19	0	16	10	9	2	12	4	5	4	0

## Oneway Analysis of Fit Score by Style

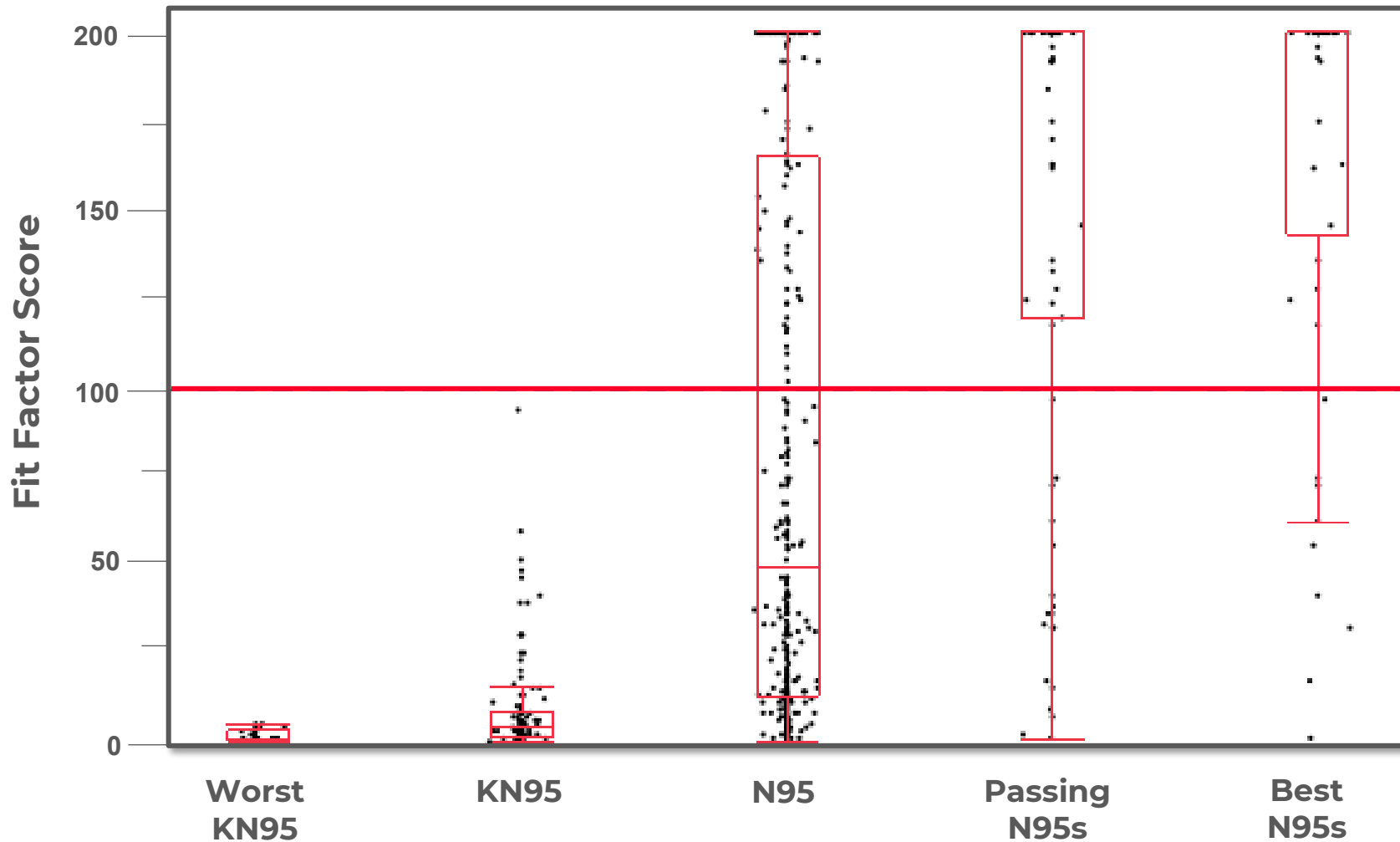


- For N95 respirators, cup designs performed better than duckbills and flat-folds, but highly variable results were seen within all styles

Style	N Rows	Median Fit Factor Score
Cup	121	113
Duckbill	100	59
Tri-Fold	50	60
Flat-Fold	74	13

# UNRELIABLE RANGE OF PROTECTION

## Oneway Analysis of Fit Score by Type

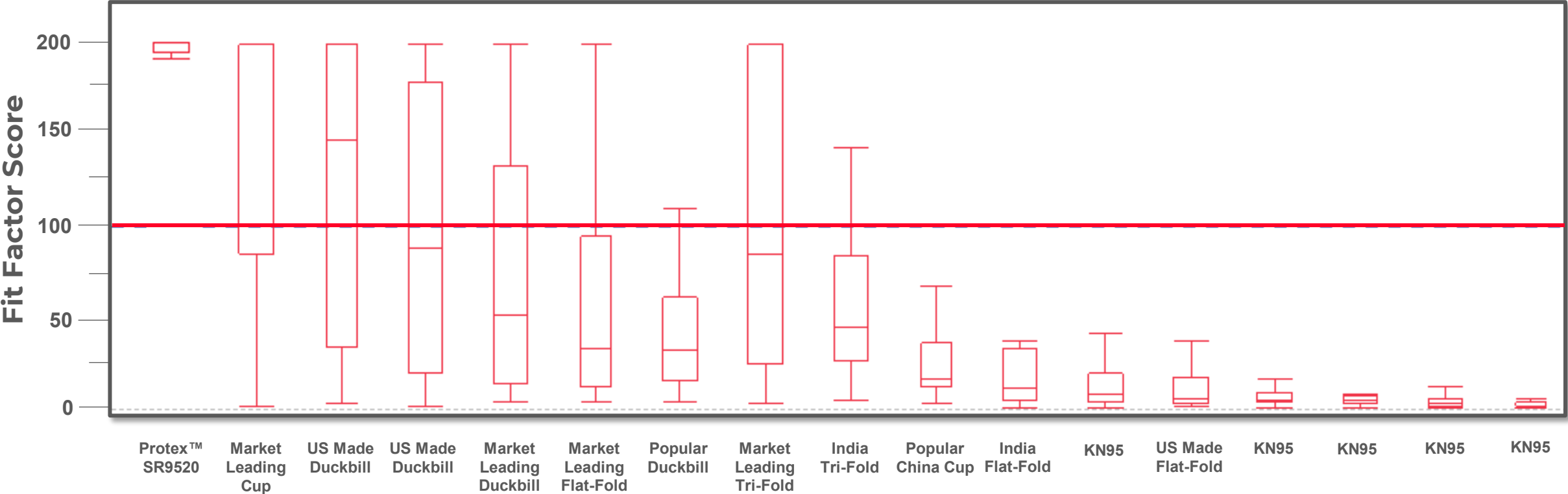


- No KN95 respirator passed a Fit Test on any individual in the panel. Of the N95s, some models performed well, but many did not.

Type	N Rows	Median Fit Factor Score
Worst KN95	27	3
KN95	106	5
N95	304	49.5
Passing N95s	78	200
Best N95s	54	200

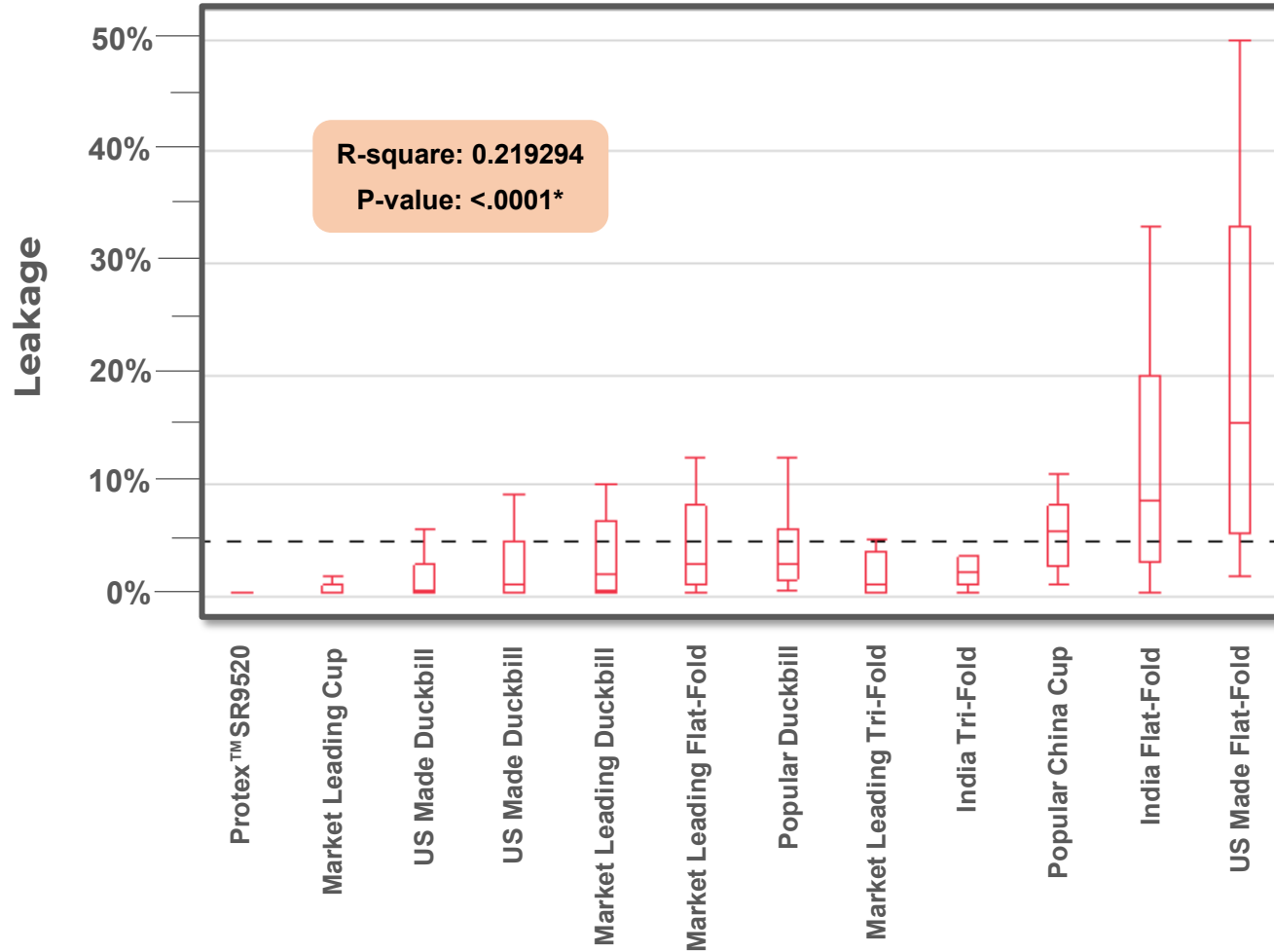
# FIT CAPABILITY IS ESSENTIAL TO UNDERSTANDING RESPIRATOR PERFORMANCE

## Variability Chart for Fit Factor Score

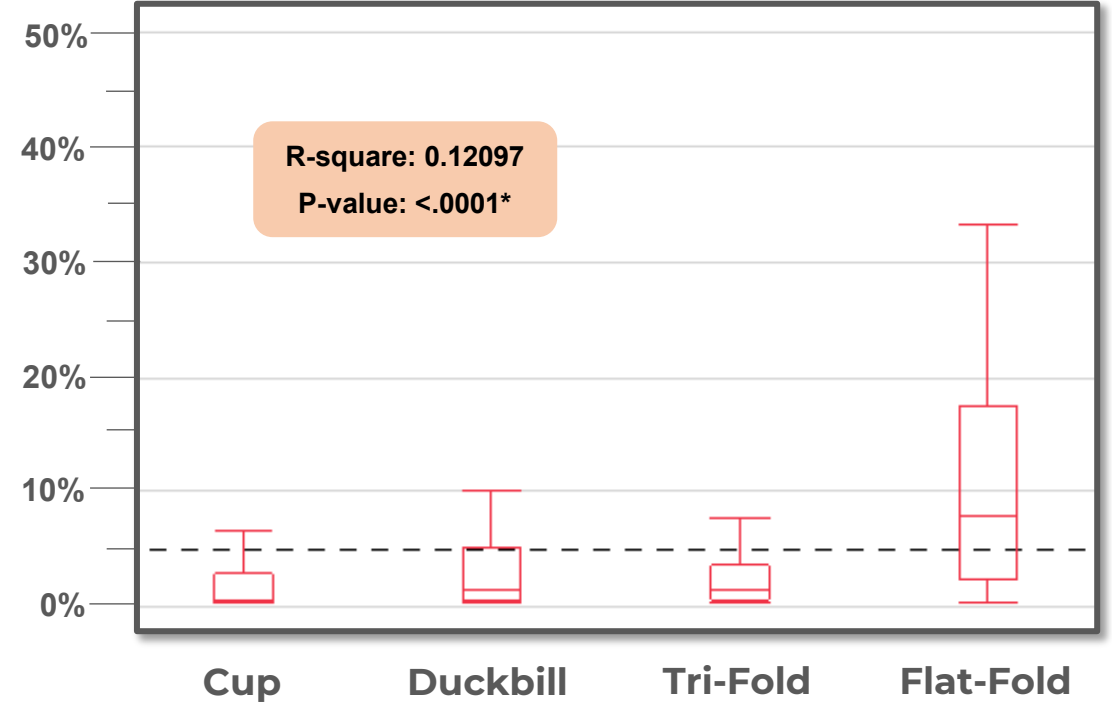


# N95 RESPIRATOR LEAKAGE ANALYSIS

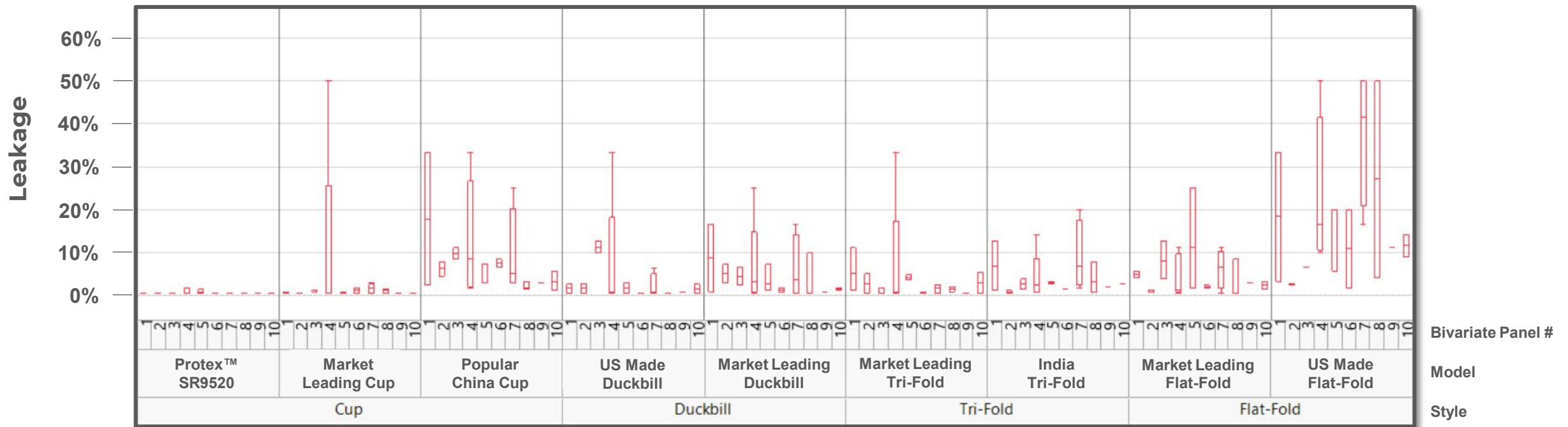
## Oneway Analysis of Leakage by Model



## Oneway Analysis of Leakage by Style



## Variability of Leakage Across Face Shapes



## Major Conclusions:

1. ASTM F3407 Standard is essential to understanding fit performance
2. There were large differences between N95 designs tested in terms of fit capability and minimum levels of protection
3. KN95s tested may pose risks to the general public and should not be conflated with N95s
4. Fit capability is essential to understanding respirator performance
5. Adoption of the ASTM F3407 standard could have public health benefits and lead to improvements in respirator design



# THANK YOU



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### Scan here for:

*Determining the  
Respirator Fit Capability of  
Shawmut’s Model SR9520  
Respirator and Three KN95  
Masks with Verified  
Filtration of 95% or More*

