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JOURNAL OF THE INTERNATIONAL SOCIETY FOR RESPIRATORY PROTECTION

JISRP

Editor in Chief

Evan Floyd, Ph.D.
Hudson College of Public Health
University of Oklahoma
Oklahoma City, Oklahoma, USA
JISRPEditor@ISRP.com

Publisher

Eva Dickson, Ph.D.
Royal Military College of Canada
Kingston, ON, Canada

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International Society for Respiratory Protection

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This Journal was edited by Evan Floyd, PhD, CIH, 801 NE 13th St, Oklahoma City, OK 73104, tel: +1-405-271-2070, JISRPEditor@ISRP.com in his personal capacity. No official support or endorsement by the University of Oklahoma is intended or should be inferred.

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Journal of the International Society for Respiratory Protection

Vol. 42, No. 2, 2025

Letter from the Editor

This issue of the JISRP features six manuscripts; two directly related to respirator fit testing, one examining the filtration efficiency of FFRs against nano-sized particulate, two addressing sizing and fit capability of FFRs and face masks within the general public, and one that suggests a regulatory framework for child-sized RPDs. I love how contributors to the JISRP continue to identify knowledge gaps and expand application of existing respiratory protection knowledge! I hope you will notice the growing need for non-occupational respiratory protection and the role the ISRP is playing in addressing these needs.

The JISRP shifted to a fully open access model in July 2024 which means we have completed our first full year under this new model; here is a brief update regarding the results. Over the past two issues, manuscript downloads have averaged 8,082 each, and full issue downloads have averaged 14,250. This is a drastic increase from our previous rates, far above our expectations and far above our peer-journals! Our next steps are to move the Journal onto the Scholastica platform which will allow us to move forward with DOI generation, improve article turn-around-time, and expand the editorial review board. Lastly, we will begin migrating our "legacy issues" onto the new Scholastica platform which will allow us to index our older articles and issue DOIs for these previously published articles.

As you read these fully open access manuscripts, please feel free to share links and tell others about these important topics. We also hope you will consider sharing your content with the JISRP readership. Collectively, we learned many lessons from the COVID-19 pandemic, and many have yet to be shared. Perhaps you have a recent conference presentation (Oxford 2024, AAAR, AIHA Connect), a case study within your workplace, a lesson-learned, or a more traditional scientific study that hasn't been shared yet? Sharing your findings with the JISRP readership will expand our knowledge and contribute to the world's leading collection of respiratory protection specialists.

All manuscript submissions must be through the Scholastica system; follow the instructions for authors found on the Journal webpage and look for the big red button to begin your manuscript submission! All published manuscripts are subject to the mandatory Open Access fees of: $1500 for non-ISRP members, $1000 for ISRP members, and $500 for student authors. Open Access fees cover the cost of publishing and making published materials available to non-society members. Please continue to send emails that are directly
for the Editor via JISRPeditor@isrp.com. I look forward to receiving your submission soon.

Sincerely,
Evan Floyd, PhD, CIH

Letter from the ISRP President

Dear ISRP Members,

As we continue to build on the momentum of recent years, I want to take a moment to reflect on where we are as a Society and, more importantly, where we are headed together.

ISRP 2024 in Oxford was a tremendous success and a reminder of the value of coming together in person to share knowledge, strengthen professional connections, and advance the use of respiratory protection worldwide. I extend my sincere thanks once again to the European Section, the organizing committee, speakers, sponsors, and attendees who made Oxford such a meaningful and engaging event.

Looking ahead, I am excited to continue this momentum as we prepare for ISRP 2026 in Montreal, Canada. Planning is well underway, and I hope each of you will consider participating—whether as an attendee, presenter, committee member, or volunteer. Montreal will provide an excellent setting to showcase the depth and diversity of expertise within ISRP and to welcome new voices into our community.

As we grow toward ISRP 2026, increased participation across the Society remains essential. I ask each of you to consider reaching out to colleagues, collaborators, students, and professionals with an interest in respiratory protection and encouraging them to join ISRP. Expanding our membership strengthens our ability to share the workload, broaden perspectives, and increase our impact globally.

Succession planning and leadership engagement also remain important priorities. The Society continues to need greater involvement at both the Executive Committee and Section levels, including a European Section Chair, Americas Section Secretary, renewed engagement within the Greater Chinese Section, and reinvigoration of the Australasian Section. Strong sections are the foundation of a strong Society, and your participation, whether through leadership roles or committee service, makes a real difference.

The Journal of the ISRP (JISRP) continues to grow and succeed, serving as a key platform for sharing research, applied practice, and advancements in respiratory protection. Publishing your work open access in the JISRP is one of the most impactful ways to support ISRP, extend the reach of your work, and contribute to the Society's mission. I encourage you to consider the journal for your research papers, technical notes, case studies, and program evaluations.

Thank you for your continued commitment to ISRP and to the field of respiratory protection. Together, we can continue building a vibrant, engaged, and globally relevant Society. Please don't hesitate to reach out if I can support your involvement in any way.

Warm regards,

Dr. Stephanie Lynch, CIH, CSP
President, ISRP
president@isrp.com

Development and Evaluation of Soft Headforms Representing Japanese Facial Features for Improved Respirator Fit Testing

Hiroki Haruta*, Hisashi Yuasa

Koken LTD., Basic Laboratory, 3-10-1 Akanedai, Hanno, Saitama, 357-0044, Japan.

* Corresponding author email: haruta@koken-ltd.co.jp

ABSTRACT

Introduction: Respirator fit is significantly impacted by facial features, which can differ greatly due to the diversity in race and ethnicity. In our previous study, we reported on a PCA panel for Japanese workers (Haruta *et al.*, 2023) that better represented the Japanese facial features, along with five corresponding digital headforms.

Objective: This report describes the construction of digital headforms into "soft headforms" with softness and elasticity parameters similar to a human face, and evaluates their respirator fit.

Methods: Using a skin softness and elasticity meter, the skin deformation curves at 10 facial points on each subject were measured to obtain softness and elasticity parameters. Based on the information obtained from the subject test, five soft headforms were developed using an elastic material. Finally, the fit factors of the soft headforms for the six respirator models were compared with those of hard headforms (plastic) with identical dimensions.

Results: In the subject test, the softness parameter values varied across various points, including the cheek and chin, whereas the elasticity parameter values were almost constant, regardless of the points. The softness and elasticity parameters of the five soft headforms were also measured, confirming that most values fell within the target ranges determined from the subject test. For the fit factor evaluation, while the geometric mean fit factors of all respirator models on hard headforms were below 100, soft headforms could achieve 100 or more, depending on the combination of headform type and respirator model.

Conclusions: The soft headforms had higher fit factors, confirming the efficacy of elastic material in improving respirator fit. However, further research is required to assess the effect of headform type and respirator model on fit factors by comparing subject groups in the corresponding facial category in the Specified PCA panel for Japanese workers.

Keywords: respiratory protection, respirator fit, headform, elastic material, facial features, skin deformation

INTRODUCTION

Respirator fit is important for ensuring respiratory protection for respirator wearers, as residual face seal leakage is a major factor allowing a large number of harmful particles to leak into a facepiece (Myers, 2000; Grinshpun *et al.*, 2009). Respirator fit is reportedly significantly affected by facial size and shape (Oestenstad *et al.*, 1990; Groce *et al.*, 2010). In the US, the NIOSH-bivariate panel using two facial dimensions and the NIOSH-PCA panel using ten facial and head dimensions were developed as new test panels based on survey facial data of the modern US workforce population (Zhuang and Bradmiller, 2005; Zhuang *et al.*, 2007), replacing the traditional Los Alamos panel (Hack *et al.*, 1974). The NIOSH-PCA panel has five facial categories (Small, Medium, Large, Short-Wide, and Long-Narrow) based on overall face size and shape. The corresponding headforms for the five facial categories in the panel were further created as 3D digital models (Zhuang *et al.*, 2010) and adopted by the International Organization for Standardization （ISO） for respirator performance testing (ISO, 2022). Since the headform models corresponding to the NIOSH-PCA panel were based on facial dimension data in the US, the development of 3D digital models in different shapes based on the facial and head dimensions of the working population in other countries with different facial shape characteristics has been reported. Yu *et al.* (2012) developed five digital headforms representing Chinese workers using anthropometric data obtained from Chinese workers, and reported that the developed medium headform differed in facial features from the NIOSH medium headform. Lee *et al.* (2024) further developed a set of five types of headforms reflecting the features of Korean faces and heads to evaluate the performance of respirators. The facial features of US and Japanese workers also differ according to their racial and ethnic diversity. In our previous study, we developed a Specified PCA panel for Japanese workers that better represented Japanese facial features (Haruta *et al.*, 2016). Additionally, using 3D scan data of Japanese subjects and a homologous modeling technique, we developed five digital models corresponding to the five facial categories in the panel (Haruta *et al.*, 2023).

The material used for headforms is also important for converting digital models into testable headforms for respirator fit testing. In prior studies, respirator fit evaluations of half-face respirators using conventional headforms made of materials stiffer or thinner than the human facial skin, such as rubber-coated, plastic, or compressible materials, have reported high leakage rates (Cooper *et al.*, 1983; Tuomi, 1985; Golshahi *et al.*, 2013).

Due to the challenges in achieving a proper face seal with conventional headforms, respirators sealed onto headforms with artificially-adjusted leak sites have been used to measure leakages within respirators (Hinds and Kraske, 1987; Rengasamy and Eimer, 2011). However, artificial leak sites may not accurately represent the actual conditions experienced by individuals wearing respirators (Krishnan *et al.*, 1994).

Studies on headforms made from silicone materials that closely resemble the human skin for evaluating respirator fit have been reported. In one such study, Joe *et al.* (2012) fabricated five types of NIOSH headforms for respirator fit testing using commercially available flexible silicone materials. They conducted fit evaluations using a negative-pressure fit tester on three respirator models in a three-size system. They found that only combinations of two sizes in one respirator model and the short-wide headform achieved measurable negative pressure conditions, while other combinations were not measurable, suggesting that different formulations of silicone or other elastic materials might be required to conduct appropriate fit testing using headforms. NIOSH also developed an advanced headform, which is the NIOSH medium headform, using a novel elastic material that mimics the softness and thickness of human facial skin. Respirator fit testing for seven respirator models was conducted under two cyclic flow conditions. Compared to studies using older headforms constructed of conventional materials, the advanced headform significantly reduced leakage from the face seal, and achieved higher fit factors (Bergman *et al.*, 2014). Moreover, For eight respirator models, a statistically significant correlation was observed between the mean log-transformed fit factors of ten subjects, including seven subjects categorized as medium in the NIOSH-PCA panel, and the medium-advanced headform (Bergman *et al.*, 2015).

Such headforms capable of accurately assessing respirator fit are not only valuable in the design and development of better respirators, but also in the investigation of the practical performance of respirators for actual hazardous substances, for which it is unfeasible to conduct fit tests on human subjects. He *et al.* (2014) previously investigated the total inward leakages of paper, wood, and plastic combustion aerosols using the medium-advanced headform equipped with one type of respirator with a P100-class filter under three cyclic breathing flow rates and five breathing frequencies. They found that both the breathing flow rate and the type of combustion aerosol had a significant effect on the total inward leakage.

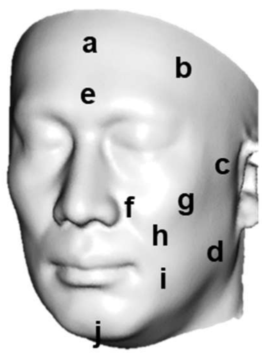
In contemporary Japan, national standards pertaining to respirator performances involve measuring the increase in carbon dioxide concentration within a facepiece (to assess dead space within the facepiece) and evaluating leakage rates for powered air-purifying respirators, which are conducted using a standardized test headform (Ministry of Health, Labor, and Welfare, 1963 and 2016). This standardized test headform in Japan comes in only one type, a rigid plastic “Hard-headform,” and is thus limited by the same issue of poor respirator fit observed in past studies using conventional headforms.

The objective of this study aimed to develop and evaluate soft headforms that represent Japanese facial features and can be used to improve to respirator fit testing. We initially investigated the physical properties of the facial skin of Japanese subjects using a skin softness and elasticity measuring device widely used in the medical and cosmetic fields. Using the obtained data as a reference, we materialized the five digital models corresponding to the facial categories in the Specified PCA panel for Japanese workers (Haruta *et al.* 2023) into five testable headforms with elastic materials referred to as “soft headform.” The performance of the respirator fit for the soft headforms was evaluated through comparison with plastic headforms (hard headforms) of identical dimensions.

METHODS

Measurement of softness and elasticity parameters on subject faces

The skin deformation curves were measured on the faces of thirty-one healthy adult subjects, aged 22–65 years, using a noninvasive skin softness and elasticity measurement device (MPA580, Courage + Khazaka Electronic GmbH, Cologne). Although the subjects were not selected based on facial type category, classification according to the previously defined PCA panel indicated that six subjects were in the Small category, 17 in Medium, three in Large, three in Short-Wide, and two in Long-Narrow. In this study, the measurements were conducted without considering facial category.



a. Forehead region
b. Frontotemporal region
c. Zygion
d. Gonion
e. Glabella
f. Nose side
g. Cheek region 1 (on zygomatic bone)
h. Cheek region 2
i. Cheek region 3
j. Chin

Figure 1. Measurement points on a face.

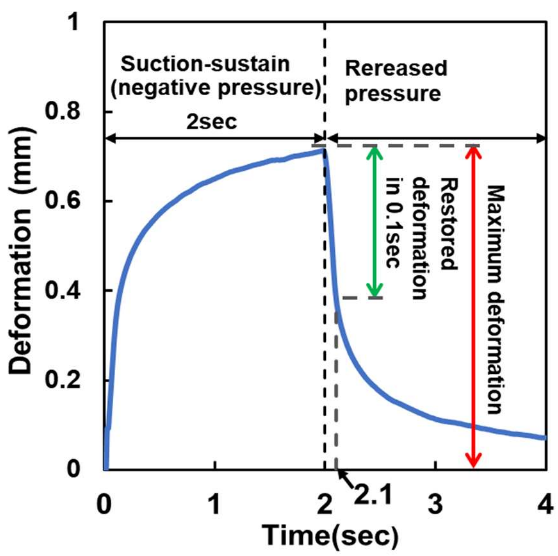


Figure 2. An example skin deformation curve and parameters.

Parameters related to softness and elasticity were subsequently calculated from the obtained skin deformation curves. The study design was approved by the Koken institutional review board. The number of measurement points on the subjects’ s faces was set to ten, as presented in Figure 1, including points considered to affect respirator fit. The device used in this study is widely used in both the medical and cosmetic fields (Courage + Khazaka Electronic GmbH. Abstracts Cutometer, 2024). To briefly describe the measurement using this device, a probe was applied to the target skin, which was suctioned using negative pressure. After a certain period, the negative pressure was released. A deformation curve showing skin deformation over time was obtained, as presented in Figure 2. By analyzing the deformation curve, parameters indicative of various physical properties of the skin can be derived. This study focused on skin softness and elasticity as properties potentially affecting respirator fit. Based on the technical documentation of the device (Courage + Khazaka electronic GmbH Instruction Manual, 2013) and previous studies that measured subjects' facial properties using the same device (Akhtar *et al.*, 2011; Kawabata *et al.*, 2012), the measurement condition for suction and holding times were set to 2 seconds, the maximum amount of deformation during decompression was determined from the deformation curve, and used as a parameter to indicate skin softness. The ratio of the recovered deformation (0.1 s after decompression release) to the maximum deformation was calculated and used as a parameter indicating elasticity. In this study, these parameters were referred to as the softness parameter R0 and elasticity parameter R7, respectively, and were employed as evaluation indices.

Fabrication of soft-headforms using an elastic material and evaluation of the softness and elasticity parameters

After obtaining data on the softness and elasticity parameters by measuring the subject faces, five types of soft headforms based on the Specified PCA panel for Japanese workers were fabricated. The headform skin layers were fabricated using an elastic silicone rubber-based material (Toughsilon®, Tanac Ltd., Gifu, Japan), which is commonly used in the medical field for artificial skin in surgical training and artificial organs. Figure 3 briefly illustrates the process from the 3D digital model data to the materialization of the soft headform. The soft headform was primarily composed of an outer elastic skin layer and a hard inner core. The 3D digital data of the headform were input to a milling machine, and a resin mold was created for the outer skin layer. The inner core model was designed using 3D computer-aided design (CAD) to ensure that the skin layer at each part of the headform face achieved the target thickness. After modeling, the core model was produced using a 3D printer. The soft headforms were created by placing the inner core model inside the resin mold and casting the elastic material into the gap between them. It should be noted that harder silicone rubber parts were embedded in the nose and ear areas of the headform, as the material used for the skin layer made them too soft. For the five fabricated soft headforms, the softness parameter R0 and the elasticity parameter R7 were measured three times at each facial point using the skin softness and elasticity meter in the same manner as in the subject test.

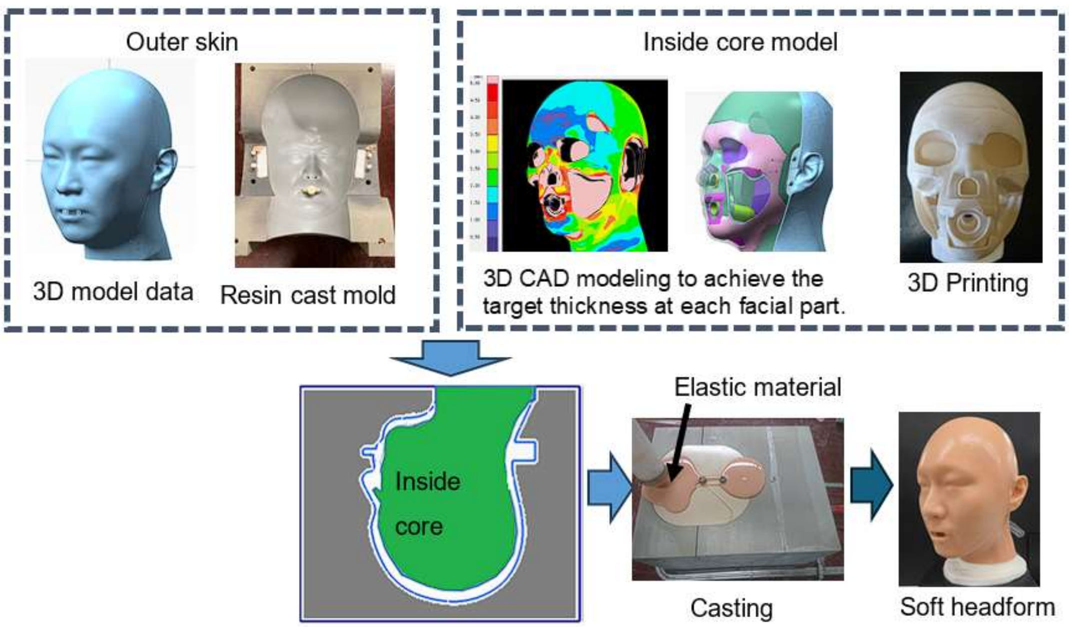


Figure 3. Overview of the process of mold making and fabrication of the soft-headform.

Evaluation of respirator fit of soft headforms

The respirator fit of the soft headforms was evaluated by comparing fit factors with those of hard headforms with identical dimensions and a conventional hard material (plastic) surface. Fit factor measurements were performed using a Mask-fitting Tester MT-05U (Sibata Scientific Technology Ltd., Tokyo, Japan). The fit factor was calculated as the ratio of the ambient particle concentration (>0.3 μm) outside the facepiece to the concentration inside the facepiece when the respirator was donned on the headform. The headforms were connected to a breathing simulator (Koken Ltd., Tokyo, Japan), while a cyclic flow with a sinusoidal waveform of 10 L/min was used as the breathing condition, assuming a static respiratory flow rate. Table I presents six commercially available half-mask respirator models used in this study, certified either under the Japanese national standard for dust masks or by NIOSH under 42 CFR Part 84, coded alphabetically without specifying product names. Given that the filter classes and certified standards differed, a preliminary verification test was conducted. Each respirator model was affixed to a test holder to ensure complete facial sealing. It was subsequently confirmed that the leakage was below the detection limit (zero count) under the same test conditions as in the headform evaluation. Consequently, it has been posited that the particles observed inside the facepiece when deposited on the headform could be attributed to the face seal. Respirators were donned on the headforms according to the manufacturer's instructions, ensuring correct head strap positioning and adjusting the nose clip as needed. Although some respirator models are equipped with fit checkers that allow wearers to perform negative or positive pressure fit checks, headforms cannot perform these checks in the same manner as human wearers. Bergman *et al.* (2014) previously reported that when evaluating the respirator fit of NIOSH-certified respirators on the advanced headform, they utilized a real-time screening of fit factors with PortaCount Pro+ (TSI Inc., Shoreview, Minnesota., USA) to preliminarily assess the respirator fit and make necessary adjustments. This screening method resulted in high fit factors, comparable to anticipated results when the respirators were worn by wearers. As such, the real-time measurement function, which was also included in the MT-05U, was utilized to don the respirators to the headforms. After donning the respirators onto the headforms and adjusting the respirator position, nose clip, and head straps, the breathing simulator generated the cyclic flow. While monitoring the fit factor values using the real-time measurement function, further adjustments were made to confirm that the respirator fit condition that stably achieved the highest fit factor. After confirming the optimal fit condition, the respirator was temporarily removed and subsequently redonned to replicate the previously confirmed optimal fit as accurately as possible, after which the actual fit factor measurement was conducted. This procedure — donning the respirator, adjusting its position and straps while monitoring fit factor in real-time, removing it, and redonning — was repeated three times by one test operator for each respirator and headform combination.

Table I. Respirator models for fit factor evaluation.

Model	Type	Class	Certification Standard
A	Filtering facepiece	N95/DS2	Japanese Standard [a]
B	Elastomeric half-mask	RL2	
C	Elastomeric half-mask	RL2	
D	Elastomeric half-mask	RL2	
E	Elastomeric half-mask	N95	NIOSH [b]
F	Filtering facepiece	P95	

[a] Japanese national standard for dust masks (Ministry of Health, Labor, and Welfare, 1963)
[b] 42 CFR Part 84 (Code of Federal Register, 1995)

RESULTS AND DISCUSSION

Softness and elasticity parameters on subject face

Table II shows the descriptive statistics for parameters R0 and R7, respectively, which were calculated from the deformation curves at each facial measurement point of the subjects. The mean R0 values varied across the measurement points, ranging from 0.53 (forehead region) to 1.12 (cheek region 3) while mean R7 values were relatively consistent ranging from 0.42 to 0.49. To observe statistically significant differences in R0, a Friedman test was conducted, which revealed significant differences among measurement points ($p<0.01$). A Scheffé post-hoc test was then conducted to classify the measurement points. Among them, the forehead region exhibited the lowest mean R0 value. Compared to the forehead, no significant differences in R0 were found for the frontotemporal region, zygion, glabella, cheek region 1, and chin ($p>0.05$ for all). In contrast, significant differences were found for the nose side and gonion (both $p<0.05$), as well as for cheek regions 2 and 3 ($p<0.01$), which showed higher mean R0 values than the forehead. For R7, the same analysis revealed no significant differences across any of the measurement points. Based on these findings, the facial measurement points were roughly grouped into three categories, as shown in Table III, and corresponding target value ranges were defined for soft headform fabrication. The target value ranges for the relatively firm and soft categories were determined based on rounded values derived from the lowest and highest mean R0 values ± standard deviations within each group. Specifically, the relatively firm category was defined as ranging from 0.4 to 0.7, based on values at the forehead and cheek region 1. The soft category was defined as ranging from 0.8 to 1.3, based on cheek regions 2 and 3. The target range for the relatively soft category was set to begin at 0.7, the upper limit of the relatively firm group, to clearly distinguish it from the firm category and the upper limit, 1.0, was based on the value observed at the gonion. The target range for R7 was uniformly set to 0.4 to 0.6 across all categories, based on values at the glabella and cheek region 2. These simplified category classifications and target values ranges were used as references in the actual fabrication of the headforms.

Table II. Descriptive statistics for parameters R0 and R7 on 10 measurement points obtained from subject faces (n=31).

	R0					R7				
Measurement point	Mean (SD)	Min	Max	95% CI (Lower)	95% CI (Upper)	Mean (SD)	Min	Max	95% CI (Lower)	95% CI (Upper)
a. Forehead region	0.53 (0.15)	0.30	0.92	0.47	0.58	0.44 (0.05)	0.31	0.55	0.42	0.46
b. Frontotemporal region	0.54 (0.14)	0.27	0.82	0.47	0.58	0.44 (0.06)	0.28	0.59	0.42	0.46
c. Zygion	0.60 (0.13)	0.37	0.89	0.55	0.64	0.44 (0.07)	0.29	0.61	0.42	0.47
d. Gonion	0.76 (0.23)	0.36	1.38	0.67	0.84	0.47 (009)	0.31	0.70	0.44	0.50
e. Glabella	0.59 (0.14)	0.35	0.87	0.54	0.64	0.42 (0.07)	0.28	0.59	0.40	0.45
f. Nose side region	0.76 (0.19)	0.26	1.07	0.69	0.83	0.48 (0.05)	0.37	0.57	0.47	0.50
g. Cheek region 1	0.62 (0.12)	0.41	0.89	0.57	0.66	0.44 (0.07)	0.30	0.59	0.41	0.47
h. Cheek region 2	0.93 (0.18)	0.67	1.33	0.87	1.00	0.49 (0.07)	0.34	0.65	0.46	0.51
i. Cheek region 3	1.12 (0.17)	0.81	1.56	1.05	1.18	0.49 (0.06)	0.36	0.58	0.47	0.51
j. Chin	0.56 (0.10)	0.40	0.77	0.53	0.60	0.45 (0.07)	0.34	0.62	0.43	0.48

Table III. Target R0 and R7 values based on measurement of subject faces.

Measurement point	Category	R0	R7
a, b, c, e, g, j	Relatively firm	0.4 - 0.7	0.4 - 0.6
d, f	Relatively soft	0.7 - 1.0	
h, i	Soft	0.8 - 1.3	

Fabrication of soft headforms using the elastic material

Figure 4 presents the deformation curves of the test plate pieces with different thicknesses of the elastic material used for the soft headform. Parameter R0, which represents the maximum deformation displacement during decompression, varied depending on the thickness of the test piece. For parameter R7, the values remained at approximately 0.5, irrespective of the thickness. Thus, by adjusting the thickness of the elastic material in each region of the headform face, the target R0 value can be approached. The thickness of the elastic material in the soft headform was determined by the gap distance between the outer mold and the inner core model. The inner core model was designed in 3D CAD, utilizing the relationship between the thickness of the test piece and R0 values as a reference (e.g., a thickness of approximately 2 mm in relatively firm regions). However, the R0 values of the headform faces after casting the elastic material often departed from the set range, requiring trial-and-error adjustments to the thickness by applying putty or sanding the inner core model. As such, the exact thickness of the elastic material in each facial region of the soft headform could not be determined. Figure 5 presents the five fabricated soft headforms with varying facial sizes and shapes. Nylon tubes were affixed to the mouth and both nostrils to facilitate connection to a breathing simulator and enable particle sampling within the facepiece.

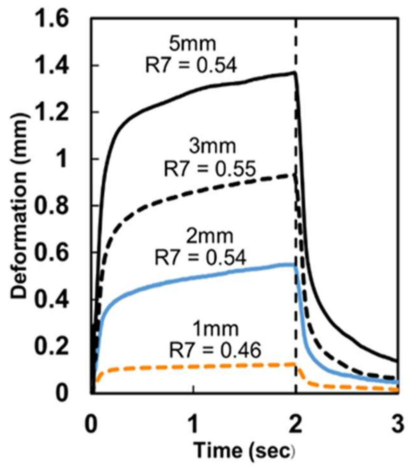


Figure 4. Deformation curves of different thicknesses of the material used for the soft headforms.

Figure 5. Five soft headforms representing the medium, and four facial categories based on the specified PCA panel, for Japanese workers. (from left to right: Medium, Small, Large, Short-Wide, and Long-Narrow)

Table IV presents the mean and standard deviations of the parameters R0 and R7 derived from the deformation curves of the facial measurement points of each soft headform, along with the predetermined target value ranges for the corresponding categories based on the subject test. In this table, bold text indicates that the mean R0 and R7 values at the given facial measurement point fall outside the corresponding target value ranges. For R0, three points — zygion and cheek regions 2 and 3 — on the Small type soft headform were found to have mean values outside the target ranges. For the Large type, cheek regions 2 and 3 also showed mean values outside the ranges. Regarding R7, only the glabella point on the Small type had a mean value outside the target range, whereas all other points on all soft headform types were confirmed to fall within the target ranges. Additionally, the conformity of the mean R0 and R7 values at each facial measurement point on each soft headform to the predefined target range was statistically evaluated using one-sample t-tests, which compared each mean value to the lower and upper bounds of the range. The results are presented in Table V. The p-values for comparisons with the lower and upper bounds are denoted by p(L) and p(U), respectively. For example, in the results for the Small type headform, the target R0 range for the forehead region, which was classified under the relatively firm category, was set between 0.4 and 0.7. The mean R0 value at the forehead region of the Small type was 0.62, which was within the target range. Since statistically significant differences ($p<0.05$) were detected when this mean was compared to both the lower (0.4) and upper (0.7) bounds using one-sample t-tests, the mean value was judged to be within the target range (0.4 < Mean R0 < 0.7). In contrast, at the zygion, the mean R0 value was 0.81, which exceeds the upper bound of the target range (0.7). Since a statistically significant difference ($p<0.05$) was also detected when compared to the upper bound, the mean R0 was judged to be significantly greater than the upper bound (Mean R0 > 0.7), indicating that it was substantially outside the target range. Similarly, at cheek region 2, the mean R0 value was 1.34, which exceeds the upper bound of the target range (1.3). However, since no statistically significant difference was detected in comparison with the upper bound ($p>0.05$), the mean was judged to be only slightly outside the target range. Furthermore, as another example, at the Frontotemporal region of the Medium type, the mean R0 value was 0.65, which falls within the target range of 0.4 to 0.7. However, since the result was not significantly lower than the upper bound of 0.7($p>0.05$), the mean was also judged to be slightly outside the target range. Based on these criteria, as shown in the table, the mean R0 values for the Small type were found to be substantially outside the target range at one measurement point (zygion) and slightly outside at two points (cheek regions 2 and 3), whereas the values at the remaining points were confirmed to fall within the target range. Similarly, for the Medium type, the mean R0 values were slightly outside the target range at two measurement points (frontotemporal region and gonion)； Large type, at three points (glabella and cheek regions 2 and 3); Short-Wide type, at four points (gonion, cheek regions 2 & 3, and chin); and Long-Narrow type, at one point (cheek region 3). At all other measurement points, the mean R0 values were confirmed within the target range. At the points where the values were outside the target range, the thickness adjustment of the elastic material achieved by modifying the inner core model was deemed inadequate. For R7, slightly outside values were observed only at two points (glabella and chin) on the Small type, one point (chin) on the Large type, and one point (chin) on the Long-Narrow type. Since these deviations were concentrated at a specific location (chin), possible causes may include the inclusion of air bubbles or mold release agent in the elastic material during casting; however, the exact reason remains unclear.

Table IV. Parameters R0 and R7 for 10 facial measurement points on each soft headform (Mean ± SD). Bold values indicate that the mean falls outside the predefined target range for the corresponding categories.

Measurement point	Parameter	Target value range	Mean R0(SD) and R7(SD)				
			Small	Medium	Large	Short-Wide	Long-Narrow
a. Forehead region	R0	0.4-0.7	0.62(0.02)	0.54(0.07)	0.52(0.03)	0.56(0.08)	0.53(0.03)
	R7	0.4-0.6	0.45(0.02)	0.53(0.04)	0.53(0.04)	0.48(0.04)	0.51(0.03)
b. Frontotemporal region	R0	0.4-0.7	0.59(0.06)	0.65(0.10)	0.56(0.06)	0.57(0.05)	0.59(0.06)
	R7	0.4-0.6	0.45(0.03)	0.51(0.04)	0.47(0.04)	0.46(0.02)	0.48(0.04)
c. Zygion	R0	0.4-0.7	**0.81(0.05)**	0.53(0.05)	0.54(0.04)	0.58(0.04)	0.58(0.05)
	R7	0.4-0.6	0.52(0.05)	0.47(0.04)	0.49(0.04)	0.54(0.03)	0.50(0.03)
d. Gonion	R0	0.7-1.0	0.93(0.03)	0.74(0.05)	0.79(0.05)	0.71(0.08)	0.81(0.06)
	R7	0.4-0.6	0.47(0.01)	0.51(0.05)	0.50(0.03)	0.49(0.01)	0.47(0.04)
e. Glabella	R0	0.4-0.7	0.51(0.04)	0.62(0.06)	0.61(0.11)	0.61(0.04)	0.58(0.06)
	R7	0.4-0.6	**0.39(0.07)**	0.50(0.05)	0.49(0.01)	0.48(0.03)	0.47(0.04)
f. Nose side region	R0	0.7-1.0	0.89(0.02)	0.92(0.02)	0.74(0.02)	0.79(0.05)	0.74(0.02)
	R7	0.4-0.6	0.51(0.05)	0.54(0.03)	0.51(0.02)	0.51(0.05)	0.51(0.05)
g. Cheek region 1	R0	0.4-0.7	0.65(0.03)	0.59(0.04)	0.53(0.07)	0.54(0.07)	0.55(0.08)
	R7	0.4-0.6	0.46(0.03)	0.54(0.02)	0.43(0.01)	0.47(0.04)	0.50(0.05)
h. Cheek region 2	R0	0.8-1.3	**1.34(0.24)**	1.11(0.05)	**1.37(0.11)**	1.27(0.12)	1.10(0.13)
	R7	0.4-0.6	0.54(0.03)	0.56(0.02)	0.52(0.03)	0.51(0.03)	0.49(0.03)
i. Cheek region 3	R0	0.8-1.3	**1.33(0.20)**	1.16(0.07)	**1.36(0.15)**	1.23(0.08)	1.12(0.14)
	R7	0.4-0.7	0.53(0.03)	0.55(0.01)	0.55(0.03)	0.49(0.03)	0.50(0.04)
j. Chin	R0	0.4-0.7	0.56(0.07)	0.65(0.04)	0.61(0.05)	0.69(0.05)	0.65(0.02)
	R7	0.4-0.6	0.41(0.02)	0.48(0.02)	0.41(0.04)	0.43(0.01)	0.42(0.03)

Table V. Result of p-values from one-sample t-tests comparing mean R0 and R7 values at each facial measurement point to the lower [p(L)] and upper [p(U)] bounds of the target range.

Measurement point	Parameter	Small		Medium		Large		Short-Wide		Long-Narrow	
		p(L)	p(U)	p(L)	p(U)	p(L)	p(U)	p(L)	p(U)	p(L)	p(U)
a. Forehead region	R0	0.001	0.010	0.003	0.030	0.007	0.003	0.032	0.044	0.009	0.006
	R7	0.025	0.003	0.012	0.034	0.017	0.046	0.036	0.015	0.001	0.004
b. Frontotemporal region	R0	0.001	0.004	0.023	**0.217**^{C}	0.025	0.032	0.014	0.021	0.018	0.043
	R7	0.047	0.007	0.024	0.030	0.039	0.012	0.021	0.003	0.041	0.023
c. Zygion	R0	0.005	**0.027**^{A}	0.023	0.014	0.011	0.008	0.009	0.019	0.014	0.027
	R7	0.023	0.049	0.044	0.016	0.025	0.020	0.013	0.038	0.011	0.010
d. Gonion	R0	0.002	0.019	**0.134**^{C}	0.006	0.043	0.008	**0.473**^{C}	0.011	0.037	0.015
	R7	0.005	0.001	0.035	0.044	0.010	0.011	0.003	0.002	0.009	0.002
e. Glabella	R0	0.020	0.006	0.002	0.012	0.043	**0.152**^{C}	0.005	0.022	0.021	0.040
	R7	**0.438**^{B}	0.016	0.041	0.037	0.001	0.000	0.023	0.013	0.042	0.012
f. Nose side region	R0	0.002	0.004	0.026	0.013	0.020	0.001	0.043	0.008	0.035	0.001
	R7	0.035	0.044	0.008	0.033	0.003	0.004	0.027	0.035	0.033	0.042
g. Cheek region 1	R0	0.002	0.041	0.009	0.000	0.042	0.026	0.031	0.026	0.045	0.041
	R7	0.030	0.005	0.003	0.021	0.018	0.000	0.044	0.016	0.036	0.032
h. Cheek region 2	R0	0.031	**0.401**^{B}	0.005	0.013	0.006	**0.202**^{B}	0.008	**0.373**^{C}	0.028	0.039
	R7	0.008	0.035	0.003	0.035	0.007	0.017	0.016	0.022	0.012	0.009
i. Cheek region 3	R0	0.023	**0.423**^{B}	0.006	0.037	0.011	**0.273**^{B}	0.004	**0.123**^{C}	0.027	**0.076**^{C}
	R7	0.010	0.029	0.001	0.007	0.005	0.044	0.012	0.009	0.019	0.019
j. Chin	R0	0.031	0.041	0.022	0.067	0.010	0.044	0.004	**0.354**^{C}	0.002	0.031
	R7	**0.309**^{C}	0.003	0.015	0.007	**0.401**^{C}	0.007	0.028	0.003	**0.183**^{C}	0.005

Bold values and superscript letters indicate the following:
A: The mean is outside the target range and shows a statistically significant difference from either the lower or upper bound.
B: The mean is outside the target range but does not show a statistically significant difference from either the lower or upper bound.
C: The mean is within the target range and does not show a statistically significant difference from either the lower or upper bound.

Respirator fit evaluation of soft headforms

Table VI presents the geometric mean fit factors (GM FF) and geometric standard deviations for both soft and corresponding hard headforms across the six respirator models. Aggregated data for all respirator models have also been included to offer a comprehensive overview of the overall trends. As fit factors typically follow a log-normal distribution, previous studies (Groce *et al.*, 2010; Bargman *et al.*, 2014) utilized logarithmic transformation for analysis. Following this approach, we also log-transformed the fit factor data and used Welch's t-test to assess differences between the soft and hard headforms; the results are summarized in the table. The respirator models used in this study were certified either under the Japanese national standard for dust masks or by NIOSH under 42 CFR Part 84; thus, achieving a fit factor >100 could be anticipated when worn by actual wearers.

All 30 combinations (six respirator models × five headform types) with hard headforms had GM FF values <100. In contrast, 17 out of the 30 combinations with soft headforms exceeded a GM FF of 100. Furthermore, except for the Small and the Short-Wide types with respirator model E, all combinations demonstrated significantly higher fit factors for the soft headforms compared to the corresponding hard headforms. This result was attributed to the elastic material used for the soft headforms, which effectively improved respirator fit.

Table VI. Geometric mean fit factor (GM FF) for hard and soft headforms by respirator models. Values in parentheses indicate geometric standard deviation (GSD).

Respirator model	Material	Small	Medium	Large	Short-Wide	Long-Narrow
A	Hard	29 (1.1)	29 (1.0)	15 (1.2)	55 (1.1)	16 (1.1)
	Soft	160 (1.2)**	316 (1.6)*	114 (1.3)**	270 (1.3)**	50 (1.3)**
B	Hard	14 (1.1)	44 (1.2)	17 (1.0)	10 (1.1)	31 (1.1)
	Soft	63 (1.3)**	291 (1.6)*	686 (2.3)*	119 (1.1)**	401 (1.6)**
C	Hard	8 (1.1)	22 (1.1)	15 (1.1)	8 (1.1)	29 (1.1)
	Soft	39 (1.0)**	128 (1.1)**	120 (1.6)*	70 (1.4)**	179 (1.3)**
D	Hard	7 (1.2)	31 (1.1)	20 (1.1)	16 (1.0)	17 (1.1)
	Soft	80 (1.3)**	184 (1.6)*	111 (1.2)**	252 (2.4)*	109 (1.5)*
E	Hard	5 (1.2)	3 (1.1)*	4 (1.0)	15 (1.1)	3 (1.1)
	Soft	13 (1.6)	27 (1.9)*	17 (1.1)**	28 (1.4)	7 (1.1)**
F	Hard	5 (1.1)	27 (1.0)	11 (1.0)	11 (1.4)	15 (1.1)
	Soft	16 (1.2)**	86 (1.4)*	118 (1.2)**	73 (1.2)**	101 (1.3)**
Total	Hard	9 (1.9)	21 (2.4)	12 (1.7)	15 (2.0)	14 (2.3)
	Soft	43 (2.5)**	131 (2.6)**	113 (3.2)**	102 (2.4)**	81 (3.7)**

* $p<0.05$ ** $p<0.01$

Additionally, among the five headform types, the Medium type was designed as the reference shape, while the other four were designed to reflect differences in facial features such as size, contours, nose, and cheek shapes. Therefore, to examine the differences in fit factors relative to the Medium type, Kruskal–Wallis tests and Shirley–Williams multiple comparisons were conducted separately by material type using log-transformed fit factors. The results are listed in Table VII.

From the Kruskal–Wallis tests, significant differences were detected in all combinations for the hard headforms, with $p<0.05$ for respirator models A, C, D, and F, and $p<0.01$ for models B and E. In contrast, for the soft headforms, significant differences ($p<0.05$) were found for models A, B, C, E, and F, whereas no significant difference was observed for model D. In the Shirley–Williams multiple comparisons using the Medium type as the reference, for the respirator model A, a significant difference was observed only in the Large type for the hard headforms, while significant differences were found in three types: Long-Narrow, Large, and Small for the soft headforms. However, for the remaining five respirator models, significant differences in the hard headforms were observed in three types (Short-Wide, Large, Small), or in four types when the Long-Narrow was additionally included. For the soft headforms, significant differences were observed only in one type, either Small or Long-Narrow. These results suggest that the soft headforms, which can deform to an extent in response to the respirator facepiece shape, may have mitigated differences in fitting, whereas the hard headforms, with their rigid and non-deformable facial surfaces, exhibited more prominent differences in the fitting between the face and facepiece due to variations in facial features. Given that the headforms were modeled in accordance with the facial size and shape categories defined in the Specified PCA panel for Japanese workers, future comparative studies involving human subjects categorized within the same facial size and shape groups may provide additional insights into the effects of headform material and facial features on respirator fit.

Table VII. Results of Kruskal–Wallis tests and Shirley–Williams multiple comparisons for differences in fit factor among headform shapes (Medium as reference).

Respirator model	Material	Kruskal–Wallis p-value	Headform Comparison (Medium vs.)	Shirley–Williams Multiple Comparisons				
				Direction	Test statics	5% critical value	2.5% critical value	Significance
A	**Hard**	0.016	Large	Medium>	2.236	1.716	2.015	**
	Soft	0.014	Long-Narrow	Medium>	2.921	1.750	2.040	**
			Large	Medium>	2.534	1.716	2.015	**
			Small	Medium>	1.964	1.645	1.960	**
B	**Hard**	0.009	Long-Narrow	Medium>	2.054	1.750	2.040	**
			Short-Wide	Medium>	3.057	1.739	2.032	**
			Large	Medium>	2.012	1.716	2.015	*
			Small	Medium>	1.964	1.645	1.960	**
	Soft	0.020	Small	Medium>	1.964	1.645	1.960	**
C	**Hard**	0.012	Short-Wide	Medium>	2.491	1.739	2.032	**
			Large	Medium>	2.012	1.716	2.015	*
			Small	Medium>	1.964	1.645	1.960	**
	Soft	0.024	Small	Medium>	1.964	1.645	1.960	**
D	**Hard**	0.012	Long-Narrow	Medium>	2.100	1.750	2.040	**
			Short-Wide	Medium>	2.038	1.739	2.032	**
			Large	Medium>	2.012	1.716	2.015	*
			Small	Medium>	1.964	1.645	1.960	**
	Soft	0.097	Small	Medium>	1.964	1.645	1.960	**
E	**Hard**	0.009	Short-Wide	Medium<	3.057	1.739	2.032	**
			Large	Medium<	2.012	1.716	2.015	*
			Small	Medium<	1.964	1.645	1.960	**
	Soft	0.036	Long-Narrow	Medium>	2.556	1.750	2.040	**
F	**Hard**	0.014	Long-Narrow	Medium>	2.054	1.750	2.040	**
			Short-Wide	Medium>	2.038	1.739	2.032	**
			Large	Medium>	2.012	1.716	2.015	*
			Small	Medium>	1.964	1.645	1.960	**
	Soft	0.0410	Small	Medium>	1.964	1.645	1.960	**
Total	**Hard**	0.0021	Long-Narrow	Medium>	2.632	1.750	2.04	**
			Short-Wide	Medium>	2.771	1.739	2.032	**
			Large	Medium>	3.115	1.716	2.015	**
			Small	Medium>	2.816	1.645	1.96	**
	Soft	0.0173	Large	Medium>	1.939	1.716	2.02	*
			Small	Medium>	3.101	1.645	1.96	**

Note: This table shows only headform types with significant differences.
* indicates that the test statistic exceeded the 5% critical value; ** indicates that the test statistic exceeded the 2.5% critical value

Study limitations

In the present study, the skin deformation data at each facial point were obtained from a limited number of subjects (n = 31). Although classification based on the previously defined PCA panel confirmed that all facial categories were represented, in this study, the skin deformation data (R0 and R7) were calculated without classifying subjects by facial category. Consequently, the calculated skin deformation data represent general trends across the overall sample and may not capture the specific characteristics of each facial category. This limitation should be considered when interpreting the representativeness and applicability of the soft headforms. In addition, the number of repeated measurements for R0 and R7 at each facial point on the soft headforms was limited to three (n = 3), which may limit the statistical power of the one-sample t-tests used to assess conformity with the target ranges. Although additional measurements could not be conducted during the course of this study, increasing the number of repetitions should be considered in future studies or similar efforts. Moreover, respirators were donned and re-donned onto headforms to achieve an optimal fit, which was monitored in advance using the real-time measurement function of the device. As this redonning was conducted by a single experienced operator, different results may have been obtained if performed by different operators. Additionally, given that only six respirator models were used, different respirator models may have yielded different results. Furthermore, the elastic material used for the headforms is a silicone rubber-based material, and the electrostatic charge of the material may influence the particle behavior in the facepiece.

CONCLUSIONS

This study aimed to develop and evaluate soft headforms based on Japanese facial features with the goal of improving the accuracy of respirator fit testing. Soft headforms based on five 3D digital models derived from the Specified Japanese PCA panel were fabricated using an elastic material. Using one-sample t-tests, the most of the softness parameter (R0) and the elasticity parameter (R7) for each facial point of the fabricated soft headforms fell within the target value ranges set as a reference based on the results of the subject test. A comparative evaluation of the respirator fit of the soft headforms with commercially available respirator models and hard headforms of identical dimensions demonstrated that the soft headforms exhibited higher fit factors in most respirator model/headform type combinations, confirming the effectiveness of the elastic material in enhancing respirator fit. Furthermore, using the Medium type as the reference, differences in fit factors among the other four headform types representing variations in facial features were analyzed using the Kruskal–Wallis and Shirley–Williams tests. As a result, significant differences between the Medium type and the other headform types were detected less frequently in the soft headforms than in the hard headforms. This result suggests that their deformable surfaces may help reduce the impact of facial shape variation on respirator fit.

The ultimate goal is to establish soft headforms as reliable surrogates for human subjects in respirator fit testing. To achieve this, further research is necessary to validate whether the fit factors obtained using these soft headforms correspond closely with those measured on actual Japanese workers. Specifically, it is essential to conduct comparative testing between the soft headforms and human subject groups representing the facial categories defined in the panel, and to determine whether there is a significant correlation in fit performance. Such findings would provide strong evidence that the soft headforms can serve as superior substitutes for traditional hard headforms in fit testing protocol.

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Performance Evaluation of a New Respirator Fit Testing Apparatus (Sibata MT-11D) against the Established PortaCount Fit Tester (TSI 8048)

Xinyi Niu[a,b] , Michael Yermakov[a], Sergey A. Grinshpun[a*]

[a]Department of Environmental and Public Health Sciences, College of Medicine, University of Cincinnati, Cincinnati, Ohio 45267-0056, USA;
[b]Department of Environmental & Occupational Health Sciences, UTHealth Houston School of Public Health, Houston, Texas, 77030, USA.

[*] Corresponding author GRINSHS@UCMAIL.UC.EDU

ABSTRACT

Efficiency of respiratory protective equipment (RPE), which is essential for protecting workers and the general public from various airborne hazards, largely relies on the quality of the faceseal. The faceseal is typically assessed using a US OSHA-accepted quantitative fit testing (QNFT). This study aimed at evaluating the performance of a newly developed respirator fit testing apparatus, the Sibata MT-11D, by comparing it with the reference TSI PortaCount® 8048 across three respirator types: N95 filtering facepiece respirators (FFRs), P100 FFRs, and half-face elastomeric respirators. Twenty-six adult participants, representing a diverse range of facial dimensions but not specially to match the NIOSH bivariate fit test panel, were recruited and trained in proper donning and doffing procedures to ensure standardized use of the respirators. Overall fit factors (FFs) were determined using the MT-11D and PortaCount® operating in simultaneously. The collected data were analyzed in accordance with American National Standards Institute (ANSI) guidelines to ensure statistical validity, including the application of exclusion zones and evaluation of test sensitivity, specificity, predictive values, and Kappa coefficients. Strong correlations were observed between the MT-11D and PortaCount® across all respirator types, with R^2 values of 0.93, 0.99, and 0.94 for N95 FFR, P100 FFR, and half-face elastomeric respirators, respectively. The test statistics met or exceeded ANSI thresholds, demonstrating the accuracy, reliability, and reproducibility of the MT-11D. These findings demonstrate that the MT-11D is a suitable device to other quantitative fit testers, capable of providing robust fit assessment for a variety of respirators in occupational and public health applications, thereby contributing to improved respiratory protection.

Keywords: Respiratory protective equipment, Quantitative fit testing, Filtering facepiece respirator, Half-face elastomeric respirator.

INTRODUCTION

Respiratory protective equipment (RPE) is employed to protect individuals from hazardous airborne contaminants. It is commonly used by occupational groups, such as healthcare workers (HCWs) and first responders, and may also be extensively used by the general public, especially during major disease outbreaks, like the recent COVID-19 pandemic. The performance of RPE depends critically on the quality of the faceseal between the respirator and the wearer's face. Therefore, respirator fit testing – either quantitative fit testing (QNFT) or qualitative fit testing (QLFT) – is conducted (generally for occupational use of respirators) to verify an adequate fit and ensure the intended sustainable level of protection. According to the U.S. Occupational Safety and Health Administration (OSHA) regulation 29 CFR 1910.134, the respirator fit testing must be performed for occupational respirator users prior to initial use and periodically thereafter, typically annually or biannually (OSHA, 1998; Clayton and Vaughan, 2005). While both QLFT and QNFT are acceptable for occupational use, QNFT provides objective, numerical data on the degree of faceseal and overall fit, which allows for precise evaluation and comparison of respirator performance.

The QNFT has evolved over several decades and is recognized as the international gold standard for objectively assessing respirator fit (Bałazy *et al.*, 2006; Lam *et al.*, 2011). Early efforts from the 1970s through the 1990s focused on improving respirator evaluation by moving beyond subjective qualitative methods that relied on a wearer's ability to detect taste or odor. QNFT became formally standardized with OSHA's 1998 Respiratory Protection Standard (29 CFR 1910.134), which established both qualitative and quantitative fit testing as acceptable approaches for occupational use. Since then, OSHA has continued expanding and refining QNFT protocols.

For many years, QNFT has been conducted using the PortaCount® fit testing system (TSI Inc., Shoreview, MN, USA), which has long served as the standard instrument for quantitative respirator fit assessment. The PortaCount® operates on the principle of condensation nuclei counter (CNC), also referred to as a condensation particle counter (CPC), in which aerosol particles are enlarged within an isopropyl alcohol–saturated environment to sizes detectable by optical means (OSHA, 2004). During testing, the instrument continuously measures aerosol particle concentrations outside (C_{out}) and inside (C_{in}) the respirator while the wearer performs a prescribed sequence of exercises to assess robustness of respirator fit. The original QNFT protocol included 8 exercises: normal breathing, deep breathing, turning the head side-to-side, moving the head up-and-down, talking, grimacing, bending over, and normal breathing again (OSHA, 2004). The fit factor (FF) for each exercise is calculated as the ratio of C_{out} and C_{in}, and the overall FF is determined as the harmonic mean of the exercise-specific values, excluding the grimace exercise (OSHA, 2004). The PortaCount® detects particles across a size range of approximately 0.02 to > 1 µm. Using these particle counts, the instrument calculates fit factors, spanning from 1 up to greater than 10,000 (TSI Inc., 2022).

In recent years, several alternatives to the PortaCount® have been developed. For example, Kanomax-Japan Inc. (Suita-city, Osaka, Japan) introduced a novel apparatus AccuFIT-9000, which, like PortaCount®, utilizes the CPC principle, but features several advancements in the design of the saturation chamber and the flow control system. The AccuFIT-9000 was evaluated with 25 subjects and three types of respirators, including an N95 filtering facepiece respirator (FFR), P100 FFR, and half-mask elastomeric facepiece produced by different manufacturers (Grinshpun *et al.*, 2021). The comparative testing and analysis showed that the AccuFIT 9000 is capable of identifying an inadequate fit of a tested respirator with a sensitivity 0.95 and specificity of 0.97. Overall, the test statistics results meet the American National Standards Institute (ANSI) guidelines (ANSI, 2010) – for all three endorsement levels: mandatory (sensitivity ≥ 0.95), advised (predictive value of a pass ≥ 0.95, specificity ≥ 0.50, and predictive value of a fail ≥ 0.50), and recommended (kappa statistics >0.70).

More recently, a new respirator fit testing apparatus, an MT-11D quantitative fit tester, was developed by Sibata Scientific Technology Ltd. (Soka, Saitama, Japan). The MT-11D employs the same CPC-based particle counting principle as the PortaCount® but incorporates several engineering and operational enhancements. It includes an air pump configuration and a proprietary software platform that allows customization of fit testing protocols, including exercise sequences and durations, to accommodate specific research or regulatory requirements. The MT-11D is capable of quantifying and displaying fit factors exceeding 200 when operating in N95 mode, enabling more precise quantification of FFRs. Such resolution is valuable in research and validation studies, as it allows for differentiation among respirators and facilitates comparative assessment of incremental improvements in fit.

In this study, the performance of the MT-11D was evaluated against the PortaCount® fit tester serving as the reference instrument. The evaluation followed the OSHA 8-exercise, quantitative fit testing protocol and adhered to ANSI guidelines (ANSI, 2010), consistent with methods used in the studies quoted above (Grinshpun *et al.*, 2021). Similar to the previous study, the present effort aimed at determining whether the MT-11D could provide fit factor measurements comparable to the PortaCount®.

METHODS

Study Participants and Tested Respirators

Prior to the beginning of the study, the University of Cincinnati Institutional Review Board (IRB) approved the study protocol. Twenty-six adult subjects, including fifteen males and eleven females, were recruited for this study. All participants had completed OSHA-required respirator medical clearance prior to testing. The subjects received standardized training in proper respirator donning and doffing prior to testing. The cohort consisted of eight Caucasian, sixteen Asian, and two African American individuals, representing a wide range of facial dimensions. Each participant's face width (bizygomatic breadth) and face length (menton-sellion length) were measured using a spreading caliper (Fabrication Enterprises Inc., White Plains, NY, USA) and plotted on the NIOSH bivariate fit test panel (Zhuang *et al.*, 2007). Most participants' facial dimensions fell within those of the NIOSH panel while five participants were identified outside the panel boundaries. The cohort spanned all facial size categories defined by the NIOSH panel – small, medium, and large. While the cohort was designed to include a diverse range of facial dimensions, it should be noted that participants were not recruited strictly according to the NIOSH bivariate panel proportions, which represents a limitation of the study.

Three types of respirators were evaluated in the study: N95 FFRs, P100 FFRs, and half-face elastomeric respirators equipped with two P100 filters (Model 2091, 3M Corp., St. Paul, MN, USA). For each type of respirator, three models produced by different manufacturers were selected for testing, as summarized in Table I. All respirators used in this study were certified for occupational use. For N95 FFR testing, both the PortaCount® (Model 8048, TSI Inc.) and Sibata's MT-11D instruments were operated in N95 mode with the N95-Companion accessory. The latter establishes a narrow particle size range by excluding the particles capable of penetrating the filter material. P100 FFRs and half-face elastomeric respirators were tested without the N95-Companion. To enable in-mask particle measurements, each respirator was fitted with a probe kit (Model 8025-N95, TSI Inc.) positioned within the breathing zone, which was connected to the fit tester during testing. A Y-splitter connected the respirator probe to both instruments, and identical sampling tubes with the same material, length, and internal diameter were used to ensure equivalence of measurements. This setup produced paired fit factor data for each exercise and overall fit factor, with one value obtained from the reference PortaCount® ($FF_{TSI\_PortaCount\ 8048}$) and one from the MT-11D ($FF_{Sibata\_MT\text{-}11D}$).

Table I. Respirators Tested in the Study.

Respirator type	Models and manufacturers	Sizes
N95 FFR	3M Model 1860, 3M Corp., St. Paul, MN, USA	One size
	3M Model 8210, 3M Corp., St. Paul, MN, USA	One size
	MODLEX Model 2200, Moldex-Metric, Inc., Culver City, CA, USA	One size
P100 FFR	3M Model 8293, 3M Corp., St. Paul, MN, USA	One size
	SAS Model 8641, SAS Safety Corp., Long Beach, CA, USA	One size
	SPERIAN Model P1130, Honeywell Inc., Charlotte, NC, USA	M/L
Half-face elastomeric respirator	3M Model 6200, 3M Corp., St. Paul, MN, USA	S/M; M/L
	Breath Buddy Model 750P3, Minor Miracle Home Solution, Coral Springs, FL, USA	M
	North 7700 Series, Honeywell Safety Products, Smithfield, RI, USA	L

Fit Testing Procedures

Respirator fit testing was performed at two locations: eleven subjects were tested in a room-size chamber at the University of Cincinnati, USA, and fifteen subjects were tested in a similar facility in Japan. Sodium chloride (NaCl) was used as the challenge aerosol. It was generated by a particle generator (Model 8026, TSI Inc.) to maintain an adequate particle concentration for quantitative fit testing. The ambient concentration range in the chamber was approximately in a range of 8,000 to 12,000 particles/cm³. It is noted that the TSI PortaCount® 8048 requires different ambient particle concentration levels for different types of respirators, e.g., while operating in N99 vs. N95 Mode. The recruited subjects randomly selected a respirator and performed the standard OSHA 8-exercise protocol while fit factors were measured simultaneously by the MT-11D and PortaCount® instruments. Both instruments were verified through daily calibration checks before fit testing.

The number of donnings and doffings was selected to satisfy the ANSI standards for evaluating fit testing methods, ensuring at least 100 data points across the cohort (ANSI, 2010). A total of 168 respirator donnings per respirator type resulted 504 donnings across the three respirator types. The study design also conformed to ANSI criteria for distribution of fit factors, including appropriate handling of the exclusion zone for $FF_{TSI\_PortaCount\ 8048}$ values between 90 and 110, sufficient representation of measurements near the required fit factor, and even distribution of $FF_{TSI\_Portacount\ 8048}$ values below the required fit factor. While the ANSI performance criteria provide benchmarks for accuracy, reliability, and reproducibility aiming for standardized comparison, they were originally developed for evaluating fit testing protocols rather than fit testing devices. The complete data collection and analysis procedures, adapted from ANSI (2010), has been detailed and discussed in previous publications (Wu *et al.*, 2017, 2018; Grinshpun *et al.*, 2021).

RESULTS AND DISCUSSION

The FF values measured by the MT-11D and PortaCount® instruments were widely distributed, spanning from 1 to 100,000 across all respirator types, as illustrated in Figure 1. This figure presents a comprehensive plot of all collected FF data for the different respirator types tested. The FF values were log-transformed to normalize the distribution and stabilize variance across the wide measurement range. It is noticed that when employing the N95-Companion, the MT-11D always provided specific FF values, including the situations when FF-value exceeded 200. On the other hand, the PortaCount® does not display the fit factor values above 200 and designated all values above this threshold as “200+.” To ensure consistency in data visualization and comparison, all “200+” readings from both instruments were standardized to 200 and the data points were plotted accordingly.

Correlation analysis revealed a strong agreement between the two instruments across all respirator types. For half-face elastomeric respirators, the overall FFs from both instruments fell well along a slope of 1.0, indicating near-perfect concordance. Although the slopes for N95 and P100 FFRs were slightly below unity (0.93 and 0.99, respectively), the correlations are strong. The P100 FFRs exhibited the highest correlation, with an R^2 of 0.99 based on the power regression model. N95 FFRs and half-face elastomeric respirators also showed high correlations, with R^2 values of 0.93 and 0.94, respectively, so that the MT-11D provides the overall FF values that closely align with those generated by the reference PortaCount®.

Application of the ANSI exclusion criteria resulted in the removal of fifteen N95 FFR measurement data points, eighteen P100 FFR data points, and six half-face elastomeric respirator data points, which fall within the exclusion zone ($FF \le 10$ and $90 \le FF \le 110$). After these exclusions, a total of 463 donnings were considered for the statistical analysis: 151 for N95 FFRs, 150 for P100 FFRs, and 162 for half-face elastomeric respirators. As summarized in Table II, all calculated test statistics, including sensitivity, specificity, predictive value of a pass, predictive value of a failure, and the Kappa coefficient, satisfied the mandatory, advised, and recommended thresholds specified by ANSI (2010). These findings confirm that the MT-11D demonstrated consistent and reliable performance under the evaluated testing conditions.

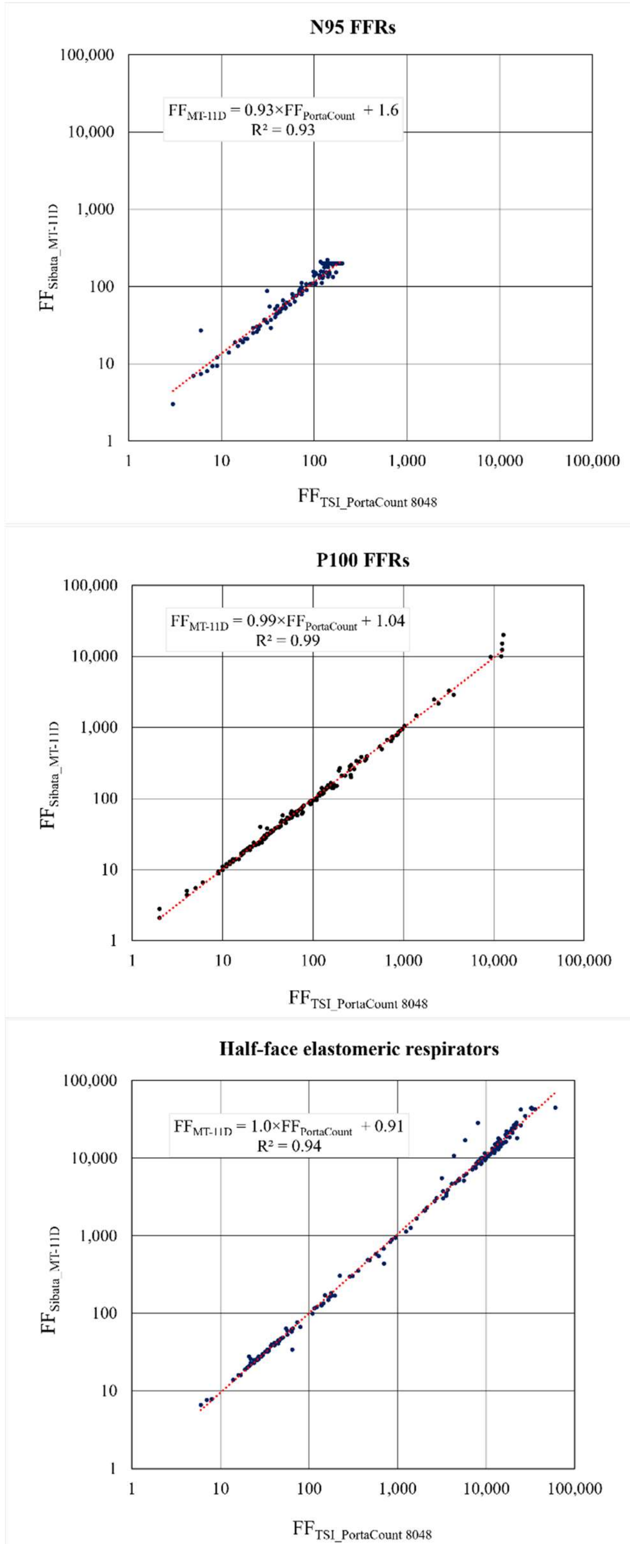

Figure 1. Comparison of FFs of N95 FFRs, P100 FFRs, and half-face elastomeric respirators measured using the reference PortaCount® and the new MT-11D. All data points, included and excluded, are plotted.

In summary, the findings highlight the MT-11D as a robust instrument for quantitative fit testing across multiple respirator types.

Table II. Statistics Summary along with the ANSI Requirements/Recommendations for Different Respirator Types.

Statistics	N95 FFRs	P100 FFRs	Half-face elastomeric respirators	ANSI requirement/ recommendation	Level of endorsement
Test sensitivity	0.96	1.00	1.00	≥ 0.95	Mandatory
Predictive value of a pass	0.98	1.00	1.00	≥ 0.95	Advised
Test specificity	1.00	1.00	1.00	≥ 0.50	Advised
Predictive value of a fail	1.00	1.00	1.00	≥ 0.50	Advised
Kappa statistics	1.00	1.00	1.00	> 0.70	Recommended

Limitations

While we have made every effort to recruit subjects with the greatest possible variety of facial dimensions, the 26 study subjects were not recruited specifically to match the NIOSH bivariate fit test panel representing 8 out of 10 cells). Additionally, although we examined a large variety of widely-used respirators, they belong to three types which feature the same assigned protection factor of 10. At the same time, several other types of respirators were beyond the scope of this study; among them are the full-facepiece air-purifying respirators with an assigned protection of 50. Future studies are being planned to address these limitations.

CONCLUSIONS

This study systematically evaluated the performance of the new MT-11D quantitative fit testing apparatus, including its N95-Companion module, in comparison with the reference PortaCount® instrument across three respirator types. The findings demonstrated strong correlations between the measurement results obtained with the MT-11D and PortaCount®, with correlation coefficients (R^2) ranging from 0.93 to 0.99, indicating a high degree of agreement. Application of the ANSI (2010) standard criteria further confirmed the validity of MT-11D as a reliable respirator fit testing device. All five key statistical performance indicators met the ANSI mandatory, advised and recommended thresholds.

ACKNOWLEDGEMENTS

The authors declare no known competing financial interests or personal relationships that could have influenced the work reported in this paper. The study was partially supported by Sibata Scientific Technology Ltd. (Soka, Saitama, Japan). This support is appreciated. The authors also gratefully acknowledge all participants for their time and cooperation during the study.

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Performance of different classes of Filtering Facepiece Respirators toward nanoparticles

C. Brochot[1*] and A. Bahloul[1]

[1] Research Department, Institut de recherche Robert-Sauvé en santé et en sécurité du travail, Montréal, Canada.

* Corresponding author E-mail: Clothilde.brochot@irsst.qc.ca

ABSTRACT

Introduction: In the case of exposure to harmful substances and the use of a filtering facepiece respirator (FFR) to protect workers, it is important to know the performance of commercial FFR. In previous studies, the authors investigated a series of parameters on the effectiveness of a standard N95 FFR: particle diameter, airflow rate intensity, breathing simulation, time of use, relative humidity. It remains uncertain whether previous results can be extrapolated to all commercial FFRs.

Objective: To determine whether previous conclusions apply to other FFRs, an expanded selection of models was evaluated in this study. The initial penetrations are then measured in order to compare the penetrations amongst the different FFRs.

Methods: To do so, an experimental setup generates NaCl nanoparticles before introducing them into a test chamber containing the FFR. A constant flow of 85 L/min is drawn through the FFR and particle concentration is measured upstream and downstream of the FFR with a Scanning Mobility Particle Sizer. This setup allows penetration to be measured as a function of the particle diameter from 10 to 200 nm. Pressure drop was also measured across the FFR.

Results: The benchmark established in this study confirms that penetration measurements align with previously reported values. All tested FFRs exhibit comparable trends: the most penetrating particle size (MPPS) remains between 30 and 50 nanometers, with penetration decreasing for particles smaller or larger than this range.

Conclusion: The results obtained thus indicate that the outcome achieved previously for the standard N95 FFRs can be extrapolated to the other FFRs presented here.

Keywords: Filtering facepiece respirators, electret, NaCl, classification, efficiency, penetration.

INTRODUCTION

In some workplaces, there are numerous exposures to chemical, biological, particulate and other substances, or mixtures. These exposures are due to the use of chemicals, hazardous substances and industrial processes, such as the use of tools or the implementation of particular tasks, all in a generally closed or semi-closed environment. Nano-sized particles are generated by manufacturing processes such as welding, combustion, vapor deposition, or gaseous phase synthesis. These particles are commonly found in the indoor air of many workplaces (NIOSH, 2021; Andraos *et al.*, 2022). Employers have become aware of the toxicity of these particles, whose diameter is less than 100 nanometers. Indeed, studies have shown that these nano-sized particles, because of their large specific surface area, exhibit greater biological activity for the same mass, making them more toxic than larger particles of the same chemical composition (Schraufnagel, 2020; Chen *et al.*, 2023). Moreover, as nanotechnologies are becoming more and more common in many work environments (automotive, aerospace, transportation, etc.), worker's exposure to these nano-sized materials is growing (NIOSH, 2021; Andraos *et al.,* 2022).

In the case of these types of exposures, employers must implement solutions to protect the health of its workers with various means of control; hierarchically ranked according to their effectiveness (NIOSH 2015). Respiratory protective devices, such as FFRs are therefore a last measure to protect workers from substances harmful to health when they are performing their work. It is thus legitimate to question their performance (filtration efficiency) against nano-sized particles. Among all commercially available FFRs, the N95 FFR is probably the most widely used device. The N95 FFR achieves high filtration efficiency – typically above 95% - through electrostatic attraction within its charged filter layers, which effectively captures nano-sized particles (Abdolghader *et al.*, 2018; Essa *et al.*, 2021; O'Shaughnessy *et al.*, 2022).

Indeed, currently and in North America, FFRs are classified according to 42 Code of Federal Regulations, part 84 (Code of Federal Regulations 1995) and CSA Z94.4.1:21 (CSA 2021). These standards classify FFRs according to the exposure aerosol (N, R and P), the minimum total efficiency of the FFR (95, 99 and 100) and, in the case of the Canadian standard, the initial pressure drop (3.43 mbar, 1.75 mbar and 1.00 mbar). With these standards, FFR are tested using charge-neutralized NaCl aerosol (for FFR classified N) and DOP aerosol (for FFR classified R or P), with an 85 liters per minute (Lpm) constant flow and up to 200 mg challenge aerosol load. For NaCl aerosol, the count median diameter (CMD) is approximately 75 nanometers, and the geometric standard deviation (GSD) is 1.86. For DOP aerosol the CMD is approximately 185 nanometers, and the GSD is 1.60. Concentration measurements upstream and downstream of the FFR are collected with a photometer or equivalent instrumentation, and the ratio of aerosol concentrations gives the penetration value. The certification criterion for N95 FFR is as follows: the total particle penetration limit is 5% (calculated in mass). The NIOSH certification test is generally tested using a TSI 8130 Automated Filter Tester. This device uses a forward light scattering photometer to measure the particle concentrations. One can note that the photometer is not capable of adequately measuring light scatter of particles below approximately 100 nanometers in diameter (Eninger *et al.* 2008), reducing the contribution of nanoscale particles to the penetration measurement. Also, certified total penetration is calculated, in mass, and does not provide information on efficiency as a function of particle diameter. Furthermore, in the case of electret media, the most penetrating particle size (MPPS) is typically less than 100 nm. In order to provide users with real performance data based on the particles they are exposed to, the most practical solution is to measure penetration as a function of particle diameter over a diameter range that includes the MPPS, i.e. between 10 and 200 nm (Rengasamy *et al.* 2011; Corbin *et al.* 2021).

Before the COVID-19 pandemic, some studies compared the laboratory performance of different FFRs (typically comparisons were between different FFRs or during fit factor measurements). But during the pandemic, studies with a benchmark approach have been published to compare the penetration of different FFRs as a function of particle size, or to compare surgical masks or homemade masks with FFRs as a function of particle size FFRs (Hao *et al.* 2020; Konda *et al.* 2020; Brochot *et al.* 2020a, 2020b; O'Shaughnessy *et al.* 2021; Zangmeister *et al.* 2020; Bourrous *et al.* 2021; Drewnick *et al.* 2021; Sharma *et al.* 2022). Since the end of the pandemic, some researchers have continued to work on respiratory protective devices, and more precisely on FFRs, but with a focus on fit (McAvoy *et al.* 2021; Ng *et al.* 2022; Freeman *et al.* 2022; Marchais *et al.* 2025), on FFR as a source-control device (Asadi *et al.* 2020; Bahloul *et al.* 2021; Yang *et al.* 2025a and 2025b) or on a hospital environment use, and especially with regard to decontamination (Peters *et al.* 2021; Kumar *et al.* 2022; Sharma *et al.* 2022; Zhu *et al.* 2022; Turgeon *et al.* 2023; Kim *et al.* 2024).

In the previous work, IRSST's working group (Institut de recherche Robert-Sauvé en santé et en sécurité du travail; the occupational health and safety research institute in Quebec, Canada) has already studied in detail the penetration of one specific N95 FFR. The authors have studied the effect of the airflow rate, the constant or cyclic breathing pattern, the time of use and the relative humidity (Bahloul *et al.* 2014; Mahdavi *et al.* 2014, 2015; Brochot *et al.* 2015, 2020a). These studies led to the development of a reliable method for measuring FFR penetration and highlighted the following trends: The MPPS for the tested N95 FFRs was approximately 50 nanometers, and the filtration efficiency exceeded 95% at 85 L/min, as required by certification. However, at higher flow rates—135, 270, and 360 L/min—the filtration efficiency dropped below the 95% threshold, reaching about 85%. A constant flow rate equal to the average breathing flow rate (Vmin) underestimates penetration compared to cyclic flow mode, while using a flow rate equivalent to the maximum cyclic flow rate (peak inspiratory flowrate, PIF) overestimates the particle penetration. The constant flow rate equivalent to the mean inhalation flow rate (MIF), i.e. 2 x Vmin, provides a better prediction of the penetration of the N95 FFR in cyclic flow mode. The MPPS shifts toward larger particle sizes as clogging increases, due to the loss of electrostatic charge in the electret media. At 10% relative humidity, penetration decreases over time, whereas at 80% relative humidity, penetration increases.

Nevertheless, the question remained whether these observations can be applied to other FFRs. In this study, the authors first compared the initial penetrations of different FFRs under conditions provided by our established setup and checked whether certain parameters could limit this comparison and interpolation. A wide variety of additional FFRs were selected from different manufacturers representing diverse characteristics: with or without exhalation valve, with different filtering surfaces, and with different classifications. The penetration of NaCl nanoparticles was measured in order to assess the penetration values for particles between 10 to 200 nm. Pressure drop was also measured for each selected FFR.

METHODS

Selected Filtering facepiece respirators (FFRs)

Twelve different commercially available FFRs were selected for this study. Table I shows the different characteristics of the FFRs, such as their class according to 42 CFR 84, their shape, their origin, and geometric surface area. All twelve FFRs contain an electret medium enclosed by other inner and outer layers in order to soften the device, protect the medium or limit the moisture inside. Also, some surface areas were evaluated and presented in Table I.

The FFR samples were randomly selected from the different boxes of FFRs stored in our laboratory and tested without conditioning.

The first FFR is the specific N95 FFR studied previously. The first six FFRs are entry-level FFRs from three different manufacturers, with N95 classification, and with and without valve. FFR_A1, FFR_A1v, FFR_A2, FFR_A2, FFR_A3, FFR_A4v, FFR_A5, FFR_A6v and FFR_A7v are from the same manufacturer and have specificities: FFR_A2 has a larger filter surface area; FFR_A3 is designed to improve the fit; FFR_A4v is conceived for a welding fume exposition; FFR_A5 is certified R95; FFR_6v is certified P95; and FFR_A7v is certified N100.

Experimental filtration performance setup

The test setup used in this study is the same presented in our previous studies (Bahloul *et al.* 2014; Mahdavi *et al.* 2014, 2015; Brochot *et al.* 2015, 2020b, 2020c, 2021). This setup was used to measure the pressure drop Δp (mbar) and the filtration efficiency E (%) of a FFR, with a 85 L/min constant airflow rate).

The setup is composed of a Collison nebulizer with 6 jets (CN 2425, CH Technologies, USA) which generate NaCl nanoparticles (NaCl concentration at 0.1% v/v). The particles are dried with a diffusion drier and brought to Boltzmann equilibrium with an 85Kr radioactive source (TSI model 3054A from TSI Inc., Shoreview, MN, USA). The polydispersed aerosol thus generated comprises particles ranging from 10 to 400 nm and centered at around 70 nm, based on the electrical mobility diameter.

Table I. Filtering Facepiece Respirators (FFRs) used in this study.

Designation	Manufac-turer	Classification according to 42 CFR 84	Surface area (cm^2± $5cm^2$)	External description
FFR_A1	Manuf. A	N 95	190	Cup shape without valve
FFR_A1v	Manuf. A	N 95	170	Cup shape with valve
FFR_B	Manuf. B	N 95	--	Cup shape without valve
FFR_Bv	Manuf. B	N 95	--	Cup shape with valve
FFR_C	Manuf. C	N 95	210	Cup shape without valve
FFR_Cv	Manuf. C	N 95	200	Cup shape with valve
FFR_A2	Manuf. A	N 95	320	Flat folded without valve
FFR_A3	Manuf. A	N 95	220	Flat folded without valve
FFR_A4v	Manuf. A	N 95	170	Cup shape with valve
FFR_A5	Manuf. A	R 95	190	Cup shape without valve
FFR_A6v	Manuf. A	P 95	170	Cup shape with valve
FFR_A7v	Manuf. A	N 100	--	Cup shape with valve

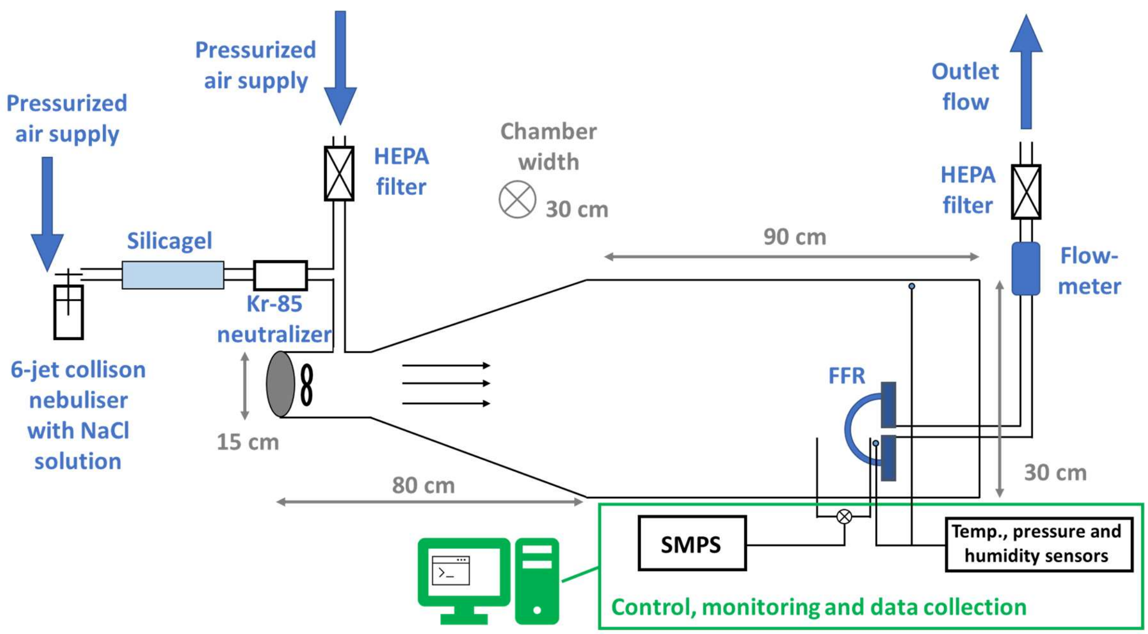

Figure 1. Experimental test bench used to measure the filtering facepiece respirators.

The aerosol is then injected into the test chamber in which the FFR is installed. The FFR is sealed onto a plate using a metal template and four fixings. The plate is coupled to a pump and set at a constant airflow rate of 85 Lpm, as recommended by 42 CFR 84 to simulate constant inhalation flow. Aerosol concentrations were then collected upstream and downstream of the FFR and directed to the Scanning Mobility Particle Sizer, SMPS (TSI Model 3080, 3081, 3775 From TSI Inc., USA) coupled with an advanced aerosol neutralizer (TSI Model 3087 From TSI Inc., USA) with measured particle size distributions across 21 channels covering a range from 10 to 200 nanometers. Three particle size distributions are collected upstream of the FFR, followed by three distributions downstream and two distributions upstream in order to verify the stability of the generation throughout the measurement. The first three concentration samples upstream and three concentration samples downstream are used to calculate the average penetration of the tested FFR, at each of the 21 channels measured by the SMPS according to Equation 1. The penetration results presented in this paper are the means and standard deviations for three samples of FFRs tested (N = 3).

$$E = 1 - P = 1 - \frac{C_{downstream}}{C_{upstream}} \quad (1)$$

The pressure drop is measured according to equation 2, using a FLUKE 922 differential pressure sensor (Fluke corp., Everett, WA, USA). This instrument has a measuring range of ± 40 mbar, with a reading accuracy of ± 1%, i.e. 0.4 mbar.

$$\Delta p = p_{upstream} - p_{downstream} \quad (2)$$

RESULTS

Comparison of initial penetration results – Effect of valve and manufacturer

Figure 2 presents penetration measurements for the first six FFRs listed in Table I. These entry-level N95 respirators, from three manufacturers, include models with and without exhalation valves. Penetration is shown as a function of electrical mobility particle diameter, ranging from 10 to 200 nanometers.

All six of these entry-level FFRs exhibited maximum penetration values below the normative limit of 5%. The MPPS was between 40 - 50 nanometers, and the presence of a valve does not affect MPPS. However, penetration increases slightly when a valve is present. For example, FFR_A1 and FFR_A1v show maximum penetrations of (2.84 ± 0.95)% and (3.85 ± 0.86)% respectively; FFR_B and FFR_Bv show (2.52 ± 0.35)% and (3.25 ± 0.09)%; and FFR_C and FFR_Cv show (2.67 ± 0.63)% and (3.13 ± 2.06)%. This increase may be explained by the valve reducing the filtration area by approximately 10–20 cm^2, which raises filtration velocity.

Overall, the valve slightly increases maximum penetration but does not alter penetration trends by particle size: MPPS remains unchanged, and penetration decreases similarly for particles smaller or larger than MPPS.

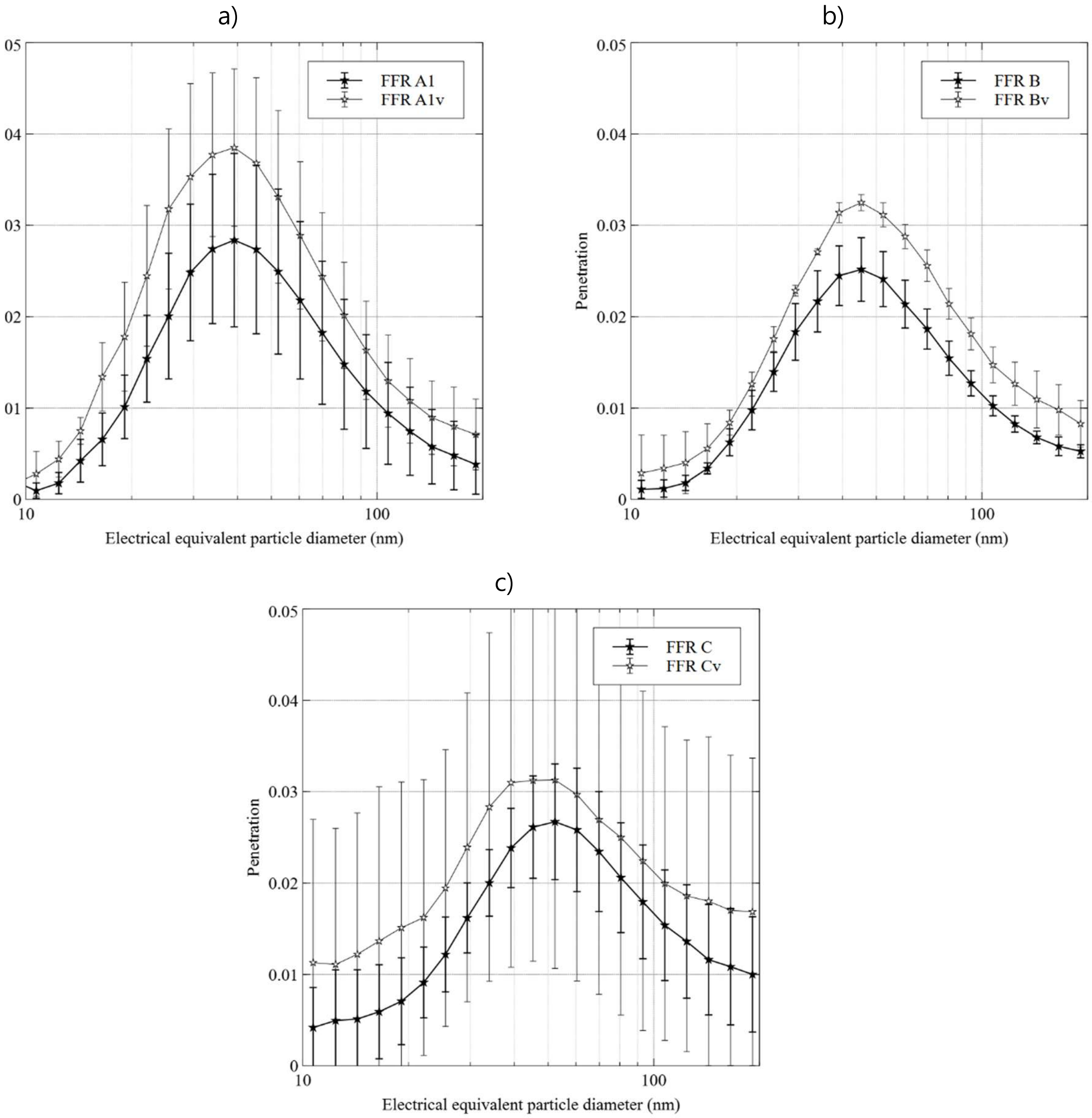

Figure 2. Mean penetrations (N = 3) ± standard deviation for a) FFR_A1 and FFR_A1v, b) FFR_B and FFR_Bv and c) FFR_C and FFR_Cv.

Comparison of penetration results at initial - N95 FFRs with different parameters

Figure 3 shows penetration measurements for FFR_A2, FFR_A3, and FFR_A4v, all produced by Manufacturer A. Gray shading represents the standard deviation of penetration for FFR_A1, included for comparison. FFR_A1 is the entry-level N95 model, while the other three have enhanced design features: FFR_A2 offers a very large filtering area to ease breathing; FFR_A3 combines a large surface with improved fit; and FFR_A4v is intended for welding fumes, incorporating additional seals for fit and a charcoal layer to reduce organic vapor concentrations.

The maximum penetration values for these three FFRs are below the normative limit of 5% and lower than those observed for FFR_A1. Their MPPS consistently are between 30 - 50 nanometers. These results indicate that design variations—such as larger filter areas or added features for specific applications—reduce maximum penetration without altering penetration trends by particle size. MPPS remains stable or slightly lower, and penetration decreases similarly for particles smaller or larger than MPPS.

Comparison of initial penetration results - Effect of classification

Figure 4 shows penetration measurements for FFR_A5, FFR_A6v, and FFR_A7v, all produced by Manufacturer A. Gray shading represents the standard deviation of penetration for FFR_A, the entry-level N95 model, included for comparison. The three respirators tested are classified as R95, P95, and N100, respectively. N-rated FFRs are intended for oil-free aerosols, while R- and P-rated models are suitable for environments containing oil-based particles—R for short-term use and P for extended use.

The maximum penetration values for these FFRs are well below the normative limit of 5% and significantly lower than those observed for FFR_A1. Their MPPS are between 30 - 40 nanometers. For FFR_A7v, classified as N100, the minimum efficiency measured was 99.98 ± 0.01%, exceeding the normative requirement of 99.97%. These results indicate that higher-efficiency ratings substantially reduce penetration without altering penetration trends by particle size. MPPS remains stable, and penetration decreases similarly for particles smaller or larger than MPPS.

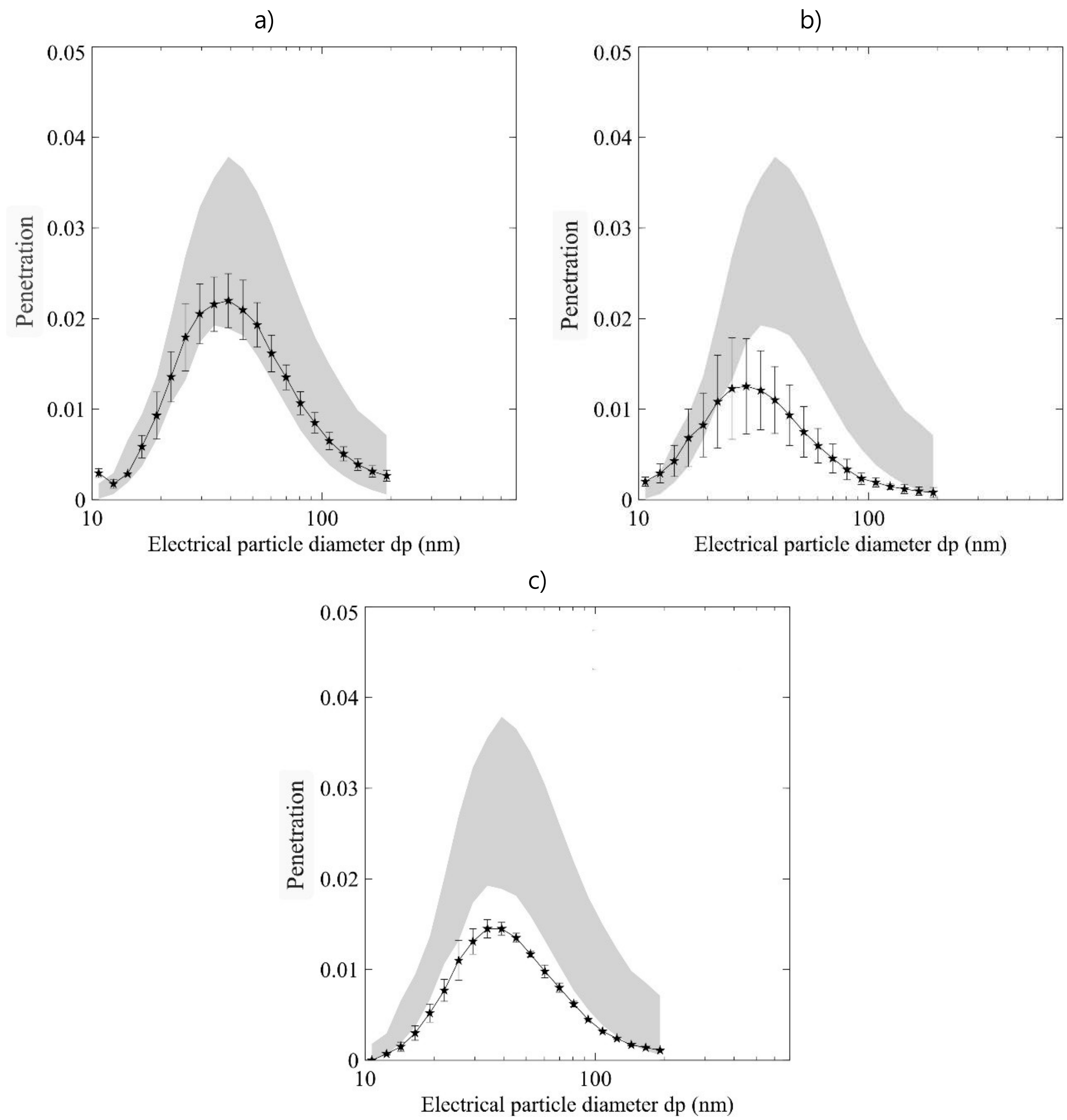

Figure 3. Mean penetrations (N = 3) ± standard deviation for a) FFR_A2, b) FFR_A3 and c) FFR_A4v (the grey area represents the average penetration (standard deviation) of FFR_A1, as reference).

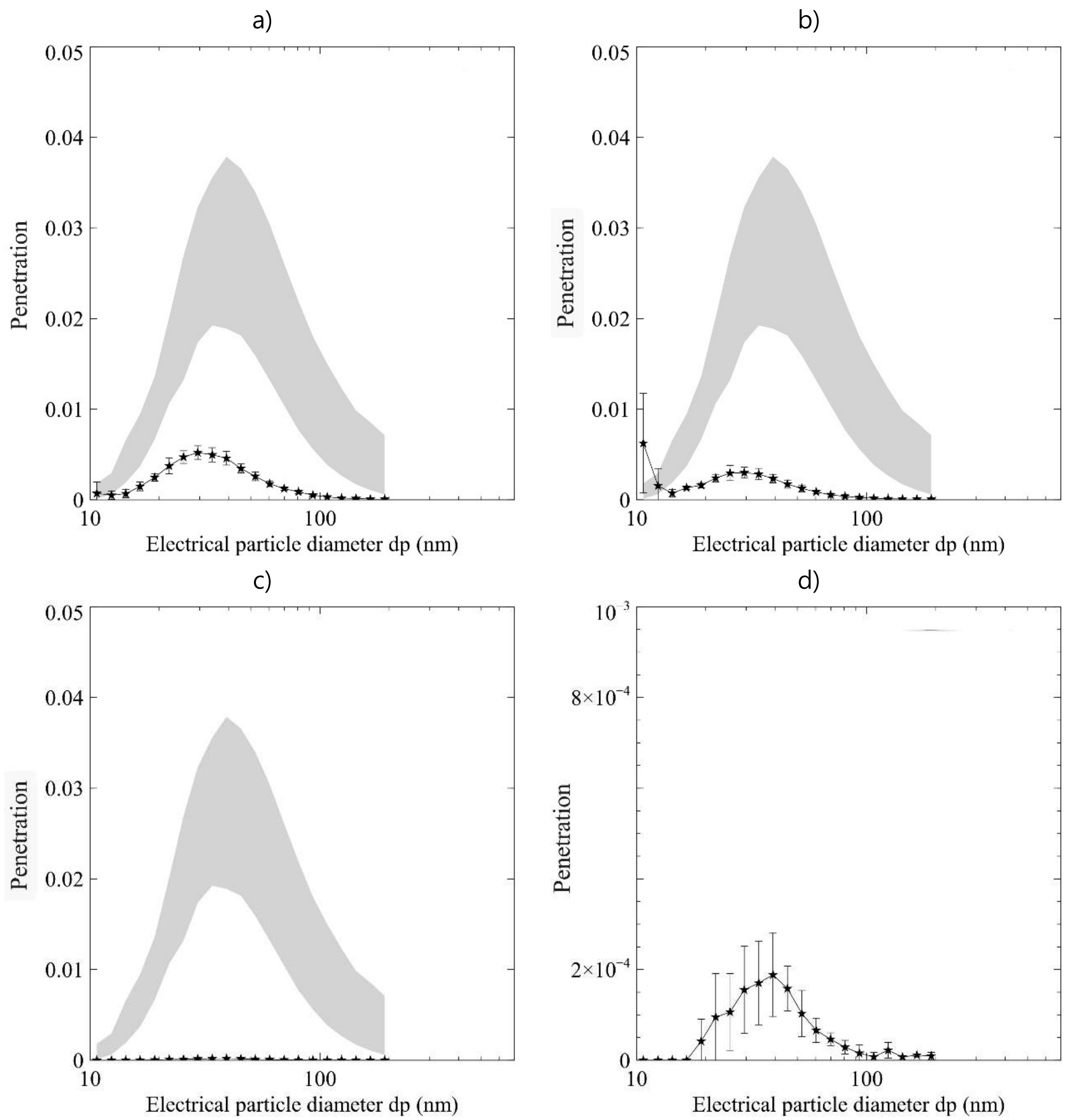

Figure 4. Mean penetrations (N = 3) ± standard deviation for a) FFR_A5, b) FFR_A6v and c) FFR_A7v with d) a zoom of FFR_A7v's penetration (the grey area represents the average penetration (standard deviation) of FFR_A1, as reference).

Comparison of pressure drops, maximum penetrations and MPPS

Table II presents the pressure drop measurements (N=3) obtained at the beginning of the penetration experiments, as well as the average maximum penetration (N=3), and the MPPS at which it was obtained. One can note that FFRs from manufacturer C exhibit higher pressure drops compared to those from manufacturers A and B. However, all measured pressure drops remain well below the normative limit of 3.43 mbar.

Table II. Pressure drops, maximum penetrations and MPPS for the 12 FFRs used in this study.

Designation	Pressure drop (mbar)	Maximum penetration (%)	MPPS (nm)
FFR_A1	0.91 ± 0.07	2.84 ± 0.95	39.2
FFR_A1v	0.98 ± 0.12	3.85 ±0.86	39.2
FFR_B	0.83 ± 0.11	2.52 ± 0.35	45.3
FFR_Bv	1.00 ± 0.06	3.25 ± 0.09	45.3
FFR_C	1.35 ± 0.04	2.67 ± 0.63	52.3
FFR_Cv	1.09 ± 0.05	3.13 ± 2.06	52.3
FFR_A2	0.34 ± 0.01	2.20 ± 0.30	34
FFR_A3	0.70 ± 0.03	1.25 ± 0.53	29.4
FFR_A4v	1.67 ± 0.15	1.45 ± 0.07	39.2
FFR_A5	0.62 ± 0.57	0.52 ± 0.07	29.4
FFR_A6v	1.24 ± 0.02	0.30 ± 0.06	29.4
FFR_A7v	1.16 ± 0.04	0.02 ± 0.01	39.2

The presence of a valve does not alter the MPPS. However, when a valve is present. Both penetration and pressure drop increases slightly. This phenomenon is likely attributable to a reduction in the effective filtration surface area caused by the valve, which consequently elevates the face velocity across the FFR. This higher velocity leads to two consequences: it diminishes particle capture efficiency particularly for nano-sized particles (Abdolghader *et al.*, 2018) and impose a higher aerodynamic resistance, resulting in higher penetration and pressure drop through the FFR.

The values in Table II also show that the difference in FFR classification (N-, R-, or P-rated), although it affects maximum penetrations and pressure drops, has very little effect on the MPPS range and the trends in the penetration curves.

DISCUSSION

The benchmark conducted in this study confirms that penetration measurements for all tested FFRs comply with normative limits and demonstrates that the setup and methodology reliably deliver expected results. Although test conditions differ slightly from normative standards, the measurements align with expected values. Additionally, this study provides detailed penetration profiles by particle size, offering precise MPPS determination and insights beyond standard certification data.

Maximum penetration values remain below 5%, and the MPPS consistently falls under 100 nanometers, typically between 30 and 50 nanometers for electret media. These results indicate similar penetration trends across different models: penetration decreases for particles smaller or larger than the MPPS, approaching zero at the extremes.

Notably, FFRs from manufacturer C exhibit higher pressure drops and MPPS compared to those from manufacturers A and B. These findings align with previously reported data for FFR_A1, suggesting that initial penetration characteristics are comparable across models under standardized conditions.

However, this study did not address variables such as filtration airflow rate, breathing patterns, clogging effects, or relative humidity. Previous research indicates these factors can influence penetration, but such conclusions cannot be generalized without further testing. Future work should explore whether variations in operational conditions or extended use affect penetration similarly across different FFRs.

CONCLUSIONS

The test setup used for this study provides reliable measurements of penetration as a function of particle size and of pressure drop, confirming compliance with normative standards and revealing consistent MPPS behavior among FFRs. These results suggest that initial performance trends observed for FFR_A1 may be extrapolated to other models under similar conditions.

Nevertheless, broader applicability requires additional research on factors such as clogging, cyclic breathing, intensity of respiration, and exposure to liquid particles. Investigating these aspects will help determine whether current findings hold under real-world conditions.

ACKNOWLEDGMENTS

The authors would like to acknowledge the IRSST (Institut de recherche Robert Sauvé en Santé et en sécurité du Travail) for the financial support of this work.

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Low-cost FFP2 respirators from the COVID-19 pandemic era – what size range do one size products actually cover?

Ikram Abdellaoui[1], David Schnura[1], Tobias Kalisch[1*]

1. Products and Work Systems, Federal Institute for Occupational Safety and Health

* Corresponding author e-mail: kalisch.tobias@baua.bund.de

ABSTRACT

Introduction*:* The poor fit of filtering face piece respirators was a contributing factor to infection during the COVID-19 pandemic. As there is no sizing system for FFP2 respirators according to the relevant European standard, product sizes can vary unpredictably. This circumstance has made it difficult to select tight-fitting respirators, particularly for people with smaller, narrower faces.

Objective: To investigate the actual size range of low-cost vertical flat-fold respirators that dominated the market during the COVID-19 pandemic and beyond.

Methods: Fifty-two one size products and 19 products with generic sizes (XS-XL) from 58 manufacturers were scanned in two dimensions and digitally measured.

Results: The one size products showed a rather narrow size distribution, since they only covered the upper third of the total size range found, thereby corresponding to size L (large). Although the average dimensions of products in generic sizes showed a systematic increase from size XS to XL, the variations observed within each size category call into question any kind of common database.

Conclusion: Given the results presented, it seems unlikely that low-cost one size respirators can effectively cover a wider range of facial dimensions. To improve the selection of tight-fitting FFP2 respirators, either specific sizes should be defined by the relevant standardization bodies or manufacturers should describe the facial dimensions of the target group for which their products are intended. At the very least, sizing metrics should be provided so that consumers can identify appropriate respirators through repeated testing. Premium products with complex designs and additional seals usually provide the required tight fit over a wide range of facial dimensions, but recent experience has shown that these products are difficult to obtain in times of market shortages.

Keywords: COVID-19 pandemic; FFP2 respirator; one size; generic size; size range

INTRODUCTION

Once all technical and organizational measures to ensure safety and health at work have been exhausted, personal protective equipment (PPE) is typically advised (Sehgal & Milton, 2021). Filtering face pieces (FFP) are disposable half-mask respirators which are used as part of PPE to protect against particulate contaminants such as dust, smoke and aerosols. Liquid aerosols and droplets, produced by talking, coughing, sneezing and breathing can contain contaminants such as viruses and bacteria (Alsved *et al.*, 2020; Drossinos *et al.,* 2021).

In the context of the COVID-19 pandemic, the use of respiratory protective equipment such as FFP, was inevitably considered one of the preventive and control measures (Liang *et al.*, 2020). In Europe, FFP respirators are classified according to the European Standard EN 149:2001+A1:2009 (CEN, 2009), which defines three graduated levels of protection based on their filtration efficiency and maximum total inward leakage. The core difference between FFP1, FFP2, and FFP3 respirators is the minimum percentage of airborne particles they are guaranteed to filter (at least 80 % for FFP1, 94 % for FFP2 and 99 % for FFP3), the maximum percentage of total inward leakage (max 22 % for FFP1, 8 % for FFP2 and 2 % for FFP3) and the assigned protection factor (up to 4 x occupational exposure limit for FFP1, up to 10 x occupational exposure limit for FFP2 and up to 30 x occupational exposure limit for FFP3). The higher the FFP number, the greater the protection.

As a result of pandemic protection measures, large sections of the population, who had not previously been trained in the use of PPE, had to deal with FFP2 respirators on a daily basis. Although the protective effect of respirators is undisputed when used correctly, the widespread use of these products during the COVID-19 pandemic has revealed some serious shortcomings in product design, selection and use. In addition to inherent product deficiencies, which have been repeatedly identified by market surveillance authorities, similar bodies and the research community (Delaloye *et al.*, 2021; Hirschwald *et al.*, 2021; Lam *et al.*, 2020), there were unanticipated effects resulting from the high demand for PPE in the marketplace (Feinmann, 2020; Livingston *et al.*, 2020; Miller *et al.*, 2021). The need for manufacturers and importers to supply extreme quantities of respirators in a short period of time, led to the production of low-cost products with simple designs. Unlike high-quality FFP2 respirators with sophisticated designs that adapt to different facial contours using seals, flexible structures and adjustable straps, these respirators must fit exactly to guarantee the claimed protective effect (Li *et al.*, 2021). Although low-cost respirators may in principle also comply with the performance requirements of the relevant European standard (DIN EN 149:2009-08 (CEN, 2009)), the lack of a sizing system means that it is not clear to the user for which face dimensions the tight fit has been verified in the certification tests.

During the COVID-19 pandemic research has suggested that an ineffective facial sealing was the primary cause of airborne contamination among mask wearers (Cooper *et al.*, 1983). Poor respirator fit is due to either a mismatch between the respirator and the face shape or a looseness of the respirator, usually due to an inability to adjust the respirator seal, or both (Hyun *et al.*, 2023). It has been shown that inadequate comfort from inappropriate products can lead to poor adherence and frequent respirator removal, further increasing the risk of infection (Hyun *et al.*, 2023; Koh *et al.*, 2022). On the other hand, where there was a known specific hazard (e.g., in a clinical setting), it was quite common to achieve a tight fit of an anatomically unsuitable respirator by increasing the contact pressure (Worsley *et al.*, 2020). This suboptimal approach poses a serious long-term risk to skin health (Abiakam *et al.*, 2021; Jiang *et al.*, 2020; Padula *et al.*, 2023; Shenal *et al.*, 2012).

As the European standard DIN EN 149:2009-08 does not specify a design or sizing system for FFP2 respirators, manufacturers are almost free to determine the dimensions of their products (CEN, 2009). During the COVID-19 pandemic, this resulted in the German market being dominated by low-cost one size respirators with two vertically folded planes and a simple design. The aim of the present study was therefore to describe the actual size range of these FFP2 respirators, which are still widely used after the end of the COVID-19 pandemic, probably due to their low purchase cost. Measurements of one size respirators and products for which the manufacturers provide size specifications are intended to demonstrate the extent to which one size dimensions overlap with the total size range of the products.

METHODS

Seventy-one certified (DIN EN 149:2009-08) FFP2 respirators from 58 different manufacturers were examined in this study, as some manufacturers had both one size respirators and respirators with a generic single size in their range. In general, FFP2 respirators are constructed of multiple layers of nonwoven material, with polypropylene and polyethylene being the base materials for the filtering layers (Juang & Tsai, 2020). In addition, an electrostatic charge is embedded in the middle layers to increase mechanical filtration efficiency (Juang & Tsai, 2020). The straps of the products studied were elastic flat or round materials (e.g., polyamide) designed as ear loops welded directly to the sides of the respirator. The nose-bridges consisted of plastic-coated wires or metal brackets as a reinforcing or shaping structure. In some models, an internal foam nose pad was attached to the inner layer. All respirators were products with a flat vertical fold and a seam welded around the perimeter. In addition to the 52 one size (OS) respirators, 19 models in generic sizes were included in the sample. These sizes were extra-small (XS, 5 products), small

(S, 3 products), medium (M, 4 products), large (L, 4 products) and extra-large (XL, 3 products). Product samples for this study were obtained from a variety of sources. These included stocks from the Federal Republic of Germany, inspection samples from the market surveillance authorities of the Federal State of Hesse, stocks from collaborating scientists who have previously conducted investigations on respirators (Hirschwald *et al.*, 2021) and complementary purchases from various German online retailers. At least 48 of the 71 products examined were available on the German market at the time of the COVID-19 pandemic (production period 2019-2020). The manufacturers' information on maximum storage life was not considered relevant for measuring the dimensions of the products.

Measuring of respirator dimensions

Each respirator was mounted on a millimeter scale carrier and scanned using a standard flatbed scanner (TA 3580ci, TA Triumph-Adler GmbH, Nuremberg, Germany). An image size of 210*297 mm (DIN A4) with a resolution of 600 dpi and a color depth of 8 bit was selected as the default setting for the scanning process. The resulting file was saved as a pdf document and analyzed using the measurement function of the Acrobat Reader software (ver. 2023.006.20320, Adobe Inc., San José, CA, USA). At the start of each measurement, the exact reproduction of lengths and surface areas in the digital image was checked against the millimeter scale for calibration. All relevant distances and the total surface area measured for each respirator are shown in Figure 1. All measurements were taken by the same research assistant to minimize variation. Reproducible recording of digital measurements was practiced in advance.

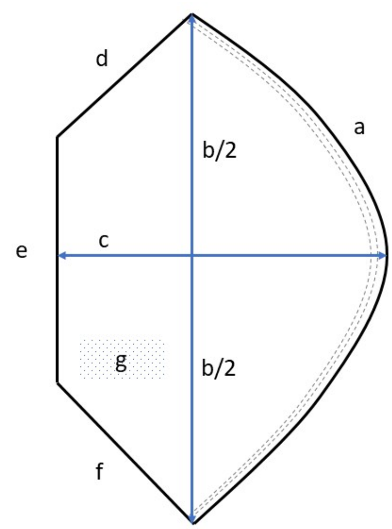

Figure 1. Schematic representation of a typical vertical flat-fold FFP2 respirator (ear loops not shown). The measured distances (face seal a, height b, depth c, edges d, e, f) and the total surface area (g) were used to classify the products. Lines c and d (blue color) intersect at right angles.

Statistical Analysis

Data were analyzed by using SPSS Statistics for Windows version 29.0 (IBM, Armonk, NY, USA) and DATAtab (DATAtab e.U., Graz, Austria). For comparative analyses, the data (distances and total surface area) of the respirators with generic size information (XS-XL) were averaged per category.

In order to investigate whether the sample of one size respirators could be divided into separate groups in terms of size dimensions, the data were examined using cluster analysis. For this purpose, a hierarchical cluster analysis was conducted using the single-linkage method with Euclidian distances. Hierarchical clustering was preferred because it inherently allows samples to be grouped into clusters that share similar characteristics and are significantly different from other clusters (Yim & Ramdeen, 2015). A dendrogram and the agglomeration scheme were used to identify a possible number of clusters. The sums of squared distances were then plotted as a function of the number of clusters and interpreted using the elbow method.

RESULTS

The average dimensions of all respirators analyzed are listed in Table I and illustrated in Figure 2 and Figure 3. Manufacturer and product names have been deliberately omitted as this information was not considered relevant to the interpretation of the data. However, this information can be made available if there is a legitimate interest.

Table I. Average size parameters of the analyzed respirators.

Size		**face seal** (a) [cm]	**height** (b) [cm]	**depth** (c) [cm]	**edge** (d) [cm]	**edge** (e) [cm]	**edge** (f) [cm]	**total surface area** (g) [cm^2]
OS	M	21.36	15.77	10.64	5.93	6.26	6.68	114.62
(N = 52)	SD	0.57	0.37	0.25	0.46	0.39	0.33	3.92
XS	M	21.35	13.61	9.76	4.38	5.78	5.64	89.60
(N = 5)	SD	2.42	0.69	1.24	0.82	0.56	0.32	3.54
S	M	20.51	13.92	9.88	5.63	5.04	5.79	96.85
(N = 3)	SD	2.01	1.24	0.67	0.38	0.95	0.80	13.71
M	M	22.46	15.03	10.50	5.20	6.46	5.97	108.86
(N = 4)	SD	2.85	0.40	1.72	1.07	0.21	1.16	16.06
L	M	21.58	15.81	10.77	6.24	6.57	6.22	113.21
(N = 4)	SD	0.84	0.21	0.87	0.23	0.58	1.07	8.43
XL	M	22.24	16.45	11.13	6.67	6.58	6.41	124.52
(N = 3)	SD	0.43	0.07	0.40	0.66	0.14	0.85	5.35

The majority of investigated products were labelled as one size (OS). Other sizes were extra-small (XS), small (S), medium (M), large (L) and extra-large (XL).

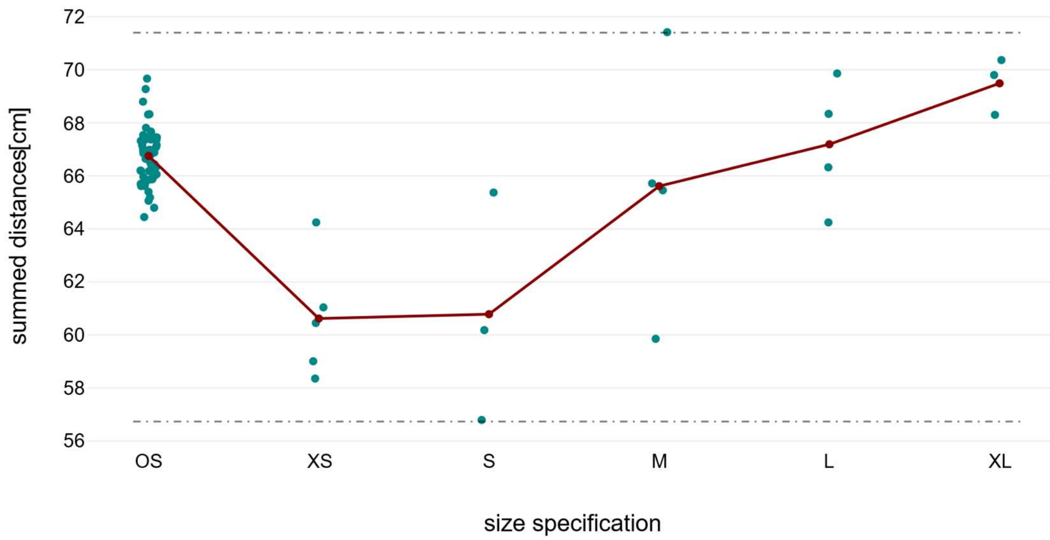

Figure 2. Multi-vari chart of summed distances (a-f) for one size (OS) and XS-XL products. Individual products are represented by green dots. The averages for each product group are shown as connected red dots. The dotted lines mark the upper and lower limits of the size range for the whole sample.

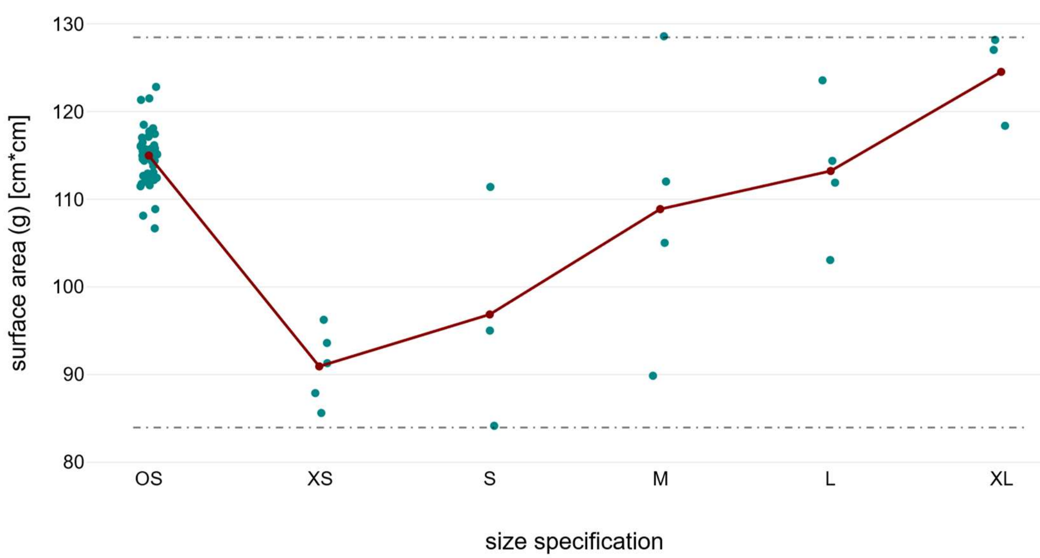

Figure 3. Multi-vari chart of total surface area (g) for one size (OS) and XS-XL products. Individual products are represented by green dots. The averages for each product group are shown as connected red dots. The dashed lines mark the upper and lower limits of the size range of the whole sample.

Correlation analysis

A correlation analysis (two-tailed Pearson's correlation) was performed to determine whether and to what extent the measured dimensions were dependent or independent of each other. Six size parameters were taken into account: face seal (a), height (b), depth (c), edges (d, e, f) and total surface area (g). Of 21 possible correlations between these individual measures, 16 were significantly correlated and only one of the correlation coefficients was negative (Table II).

Table II. Correlation analysis of size parameters of all investigated products (N = 71).

		height (b)	**depth** (c)	**edge** (d)	**edge** (e)	**edge** (f)	**surface area** (g)
face seal (a)	r	0.210	0.533**	-0.292*	0.264*	0.181	0.467**
	P	0.079	<0.001	0.014	0.026	0.131	<0.001
height (b)	r		0.551**	0.582**	0.583**	0.513**	0.884**
	P		<0.001	<0.001	<0.001	<0.001	<0.001
depth (c)	r			0.254*	0.271*	0.549**	0.760**
	P			0.032	0.022	<0.001	<0.001
edge (d)	r				0.052	0.039	0.441**
	P				0.667	0.745	<0.001
edge (e)	r					0.030	0.468**
	P					0.802	<0.001
edge (f)	r						0.599**
	P						<0.001

r = Pearson's correlation coefficient; p = significance level (two-tailed) * p≤0.05, ** p≤0.01.

A high degree of correlation between the investigated size parameters was found (76.18 % of all possible correlations, r≥0.254, p≤0.032). The total surface area (g) and the depth (c) were correlated with all other size parameters (h: r ≥ 0.441, p ≤ 0.001, c: r ≥ 0.254, p ≤ 0.032). The height (b) was correlated with five out of six other size parameters (r ≥ 0.513, p ≤ 0.001). The edges (d, f) and the face seal (a) were correlated with four out of six other size parameters (r ≥ 0.292, p ≤ 0.014), and edge f was correlated with three out of six size parameters (r ≥ 0.513, p ≤ 0.001).

Cluster analysis

Based on the dendrogram of a hierarchical cluster analysis (single-linkage method for Euclidian distances of the parameters of face seal (a), height (b), depth (c), edges (d, e, f) and total surface area (g)) a three-cluster solution could be considered for segregation of the data (Figure 4).

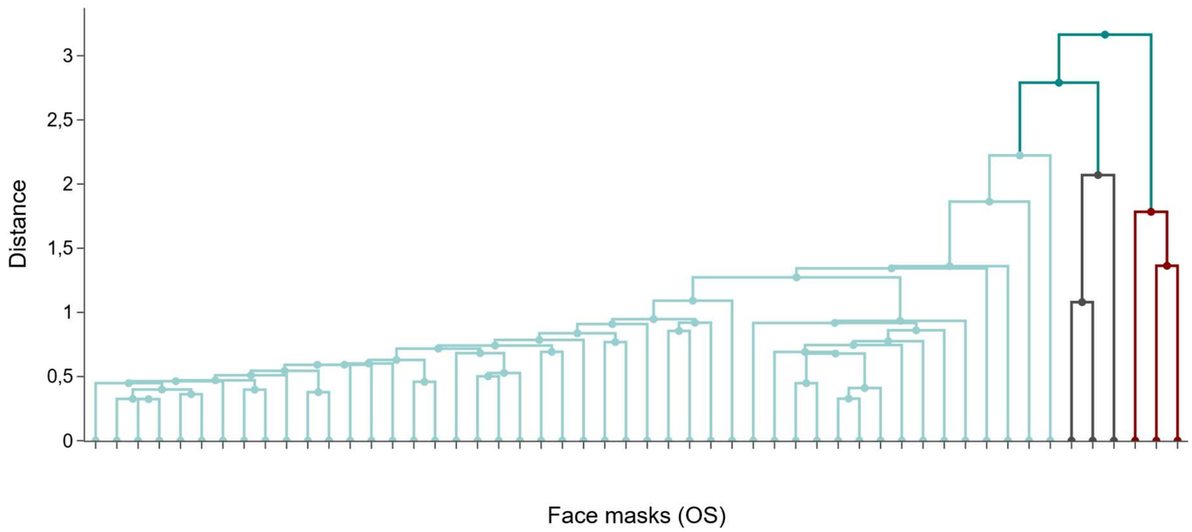

Figure 4. The cluster dendrogram based on the investigated 52 respirators in one size (OS) dimensions. The analysis revealed one main cluster (N = 46, depicted in light green) and two small subclusters (N = 3 each, shown in grey and red).

The corresponding elbow plot was analyzed for possible solutions with less than 10 clusters, as the number of measured respirators did not seem suitable for an even more detailed classification. In this context, a three-cluster solution appeared as a possible classification of the studied respirators in one size dimensions.

However, these clusters were not of comparable size, but were rather one main cluster (N = 46) and two subclusters, containing significantly fewer masks (N = 3 for each). According to the centroid data the main cluster (N = 46) is located in an intermediate position of the one size range. The two other clusters (N = 3 for both) are located above and below this position. The data of the respective centroids were transformed as a percentage of the maximum size expression per parameter (**Table III**). These data formed the basis for a subsequent test for significant difference between the centroids. However, the Kruskal-Wallis test for independent samples revealed no significant difference (H (2) = 4.224; p = 0.121).

Table III. Centroid data of the three-cluster solution for one size respirators (N = 52).

Centroid data [cm / cm^2]	**Cluster 1** (N = 3)	**Cluster 2** (N = 46)	**Cluster 3** (N = 3)
face seal (a) (% max)	20.54 (91.2)	21.42 (95.1)	22.17 (98.4)
height (b) (% max)	15.33 (92.0)	15.79 (94.8)	16.31 (97.9)
depth (c) (% max)	10.43 (89.6)	10.65 (91.5)	10.95 (94.1)
edge (d) (% max)	6.19 (80.4)	5.92 (76.9)	6.16 (80.1)
edge (e) (% max)	5.73 (80.8)	6.30 (88.9)	6.30 (88.9)
edge (f) (% max)	6.60 (88.5)	6.66 (89.3)	6.90 (92.5)
surface area (g) (% max)	107.88 (87.9)	114.99 (93.6)	121.87 (99.2)
median (% max)	**88.47**	**91.48**	**94.06**

As the significance test does not support a division of the one size respirators into three separate clusters, they can be interpreted as products in a single homogeneous size category. Figure 5 shows the distribution of the three size parameters height (b), depth (c) and total surface area (g) for all one size products in relation to the average values for the products with generic sizes (XS-XL).

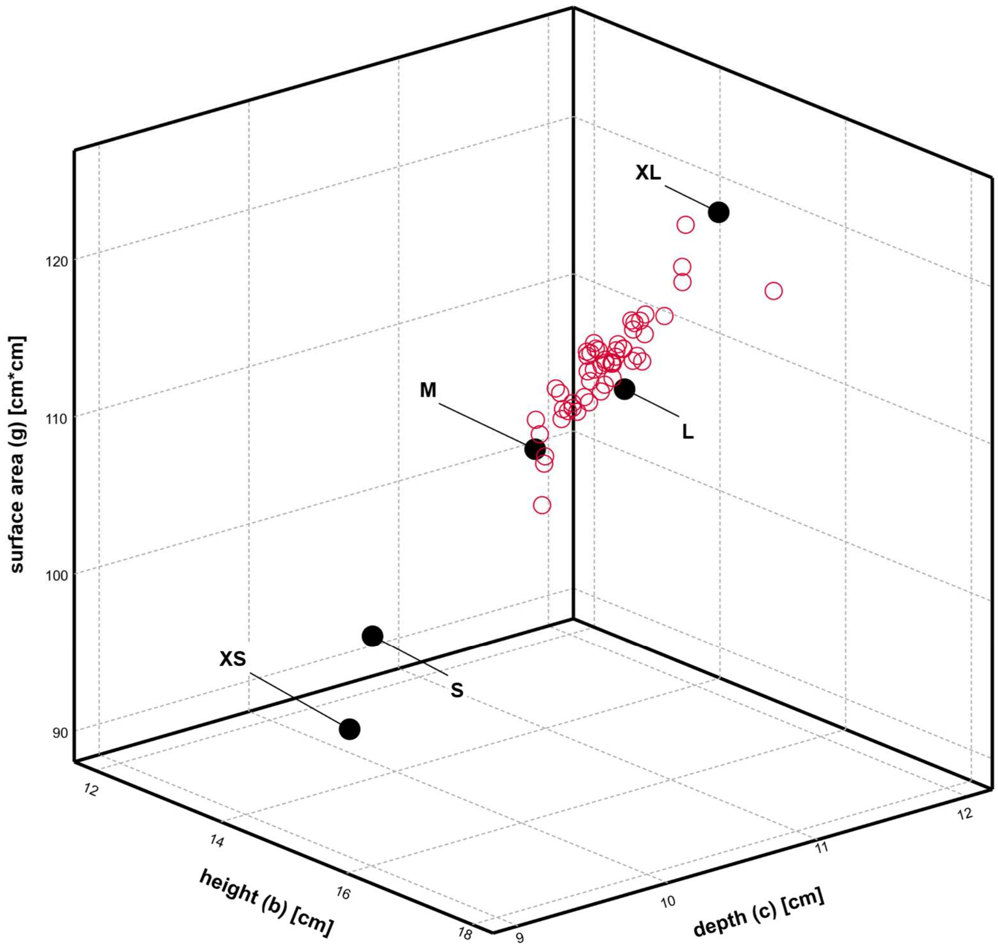

Figure 5. Three-dimensional depiction of the size parameters height (b), depth (c) and surface area (g) for respirators in one size dimensions (red circles, N = 52). The corresponding data were also shown as average values for masks in generic sizes XS to XL (black circles with labelling, N = 19).

DISCUSSION

The aim of the present study was to investigate actual size range of low-cost vertical flat-fold FFP2 respirators which have taken a large share of the market since the COVID-19 pandemic, at least in Germany. The analyses focused on one size respirators, but a smaller number of generic size masks was also examined for reference. The results presented show that the distribution of size parameters of the one size products investigated is rather narrow, as they only covered the upper third of the total size range found. Respirators in the generic sizes XS, S, M, L and XL which were only available in small quantities, showed a large within-group variation that precluded meaningful statistical group comparisons. The high degree of correlation between the size parameters examined for all respirators suggests that the size variations observed may be due to the simple scaling up or down of a standardized basic design, rather than adaptation of the products to fit faces with different anatomy.

The COVID-19 pandemic created a situation in which large segments of the population outside the typical target group for respiratory protection were using these products (Knobloch *et al.*, 2023). Reports of problems with the commercially available respirators came not only from inexperienced users, but also from professional healthcare workers (Knobloch *et al.*, 2023). In addition to general care and nursing, the focus of the investigations was particularly on areas with aerosol-generating procedures of high relevance to medical fields such as dentistry or speech therapy (Li *et al.*, 2022). Both, the monitoring of fit test results in clinical settings (Knobloch *et al.*, 2023) and targeted anthropometric analyses between people who pass a fit test and those who do not (Gakhal *et al.*, 2024; Wangsan *et al.*, 2025) have shown that people with narrow and smaller faces in particular have problems finding a tight-fitting respirator.

More recently, Caggiari *et al.* conducted a multicenter quality improvement study to investigate the factors associated with FFP3 respirator fitting outcomes during the early phase of the COVID-19 pandemic in England (Caggiari *et al.*, 2023). Their data described fitting outcomes from multiple respirator models completed by over 5000 healthcare workers. Multivariate analyses revealed that females and non-white ethnicities had significantly lower fit test pass rates compared to Caucasian males (Caggiari *et al.*, 2023). These findings are consistent with other studies that have shown lower fit test pass rates for black and Asian women (Carvalho *et al.*, 2021; Chopra *et al.*, 2021). In particular, the Asian population has consistently shown higher fit test failure rates in a variety of contexts, which has long been recognized (Han, 2000; Han & Choi, 2003; Huh *et al.*, 2018; Kim *et al.*, 2003; Lin & Chen, 2017; Yu *et al.*, 2014; Zhang *et al.*, 2020). A recent study by Wangsan *et al.* investigated fit tests results of respirators of different designs commonly used by healthcare personnel in Thailand (Wangsan *et al.*, 2025). In addition to three-panel flat-fold respirators and cup-shaped respirators, vertical flat-fold products were also tested. The pass rates for the first two respirator designs were significantly higher at 82.5 % and 51.1 % than for the vertical flat-fold respirators (5.4%). The fit factor showed even more dramatic differences. While the three-panel flat-fold respirators achieved a median FF of 191 during all tests and the cup-shaped products still achieved a median FF of 104, a median FF of 25 was measured for the vertical flat-fold respirators (Wangsan *et al.*, 2025). A common conclusion of the aforementioned studies is that currently available, simple designed respirators are not sufficient to account for the full range of anthropometric variations in an ethnically diverse workforce. From our own observations, we found that low-cost respirators with a simple design had only a small market share before the COVID-19 pandemic, as high-quality products were predominantly used in professional occupational safety.

As human facial morphology is extremely diverse and depends on many factors such as biological sex, ethnicity, age and body-mass-index (BMI) (Caggiari *et al.*, 2023; Roberge *et al.*, 2006; Zhuang *et al.*, 2010), the process of selecting a well-fitting respirator is not trivial (Regli *et al.*, 2021). Although these facts have been known for some time, little research has been carried out on the relationship between anthropometric parameters and the tight fit of respirators prior to the COVID-19 pandemic (Chopra *et al.*, 2021). In occupational health and safety, the tight fit of a respirator is ensured by qualitative fit testing or quantitative fit testing (Regli *et al.*, 2021). If a particular fit test is not passed, it is typically recommended that another product (i.e., a different design or manufacturer) is tried. In principle, this process requires a supply of respirators in various sizes and styles (Fakherpour *et al.*, 2023), which was difficult to achieve for healthcare professionals during the COVID-19 pandemic and even more difficult for private users. Apart from the fact that most private users had no real idea of the importance of a good fit and there was no way to reliably check the tight fit, the supply of products in different sizes or designs was unpredictable (Park *et al.*, 2020). A recent review showed that the design of FFP2 respirators has a significant impact on passing quantitative fit tests in a professional setting (Knobloch *et al.*, 2023). Based on data from 29 studies and a total of 18,593 fit tests performed, it was found that dome-shaped respirators (triple-panel folded respirators and rigid preformed respirators), which are primarily used in occupational safety, provided a tight fit in an average of 77 % of all fit tests performed. In contrast, flat-folded respirators (either vertically or horizontally), which have been available mainly since the COVID-19 pandemic, provided a tight fit in an average of only 31% of all tests. However, these results related to FFPs with head straps. In contrast, vertical flat-fold respirators with ear straps, which were the most commonly used products during the COVID-19 pandemic in Germany, passed the fit test in only 1.9% of cases (Knobloch *et al.*, 2023). In the light of these findings, it is all the more serious that leakage of the face seal has a greater impact on respirators with a higher filtration efficiency (e.g., FFP2/FFP3) than on respirators with a lower filtration efficiency (e.g., FFP1) (Fakherpour *et al.*, 2023). If the breathing resistance of the filter fabric is high, the air will always preferentially flow through the leaks rather than through the filter fabric during inhalation and exhalation (Chen & Willeke, 1992) which is highly relevant to infection control (Schmitt & Wang, 2022).

Our data provide an explanation for why many people had problems finding a well-fitting respirator during the COVID-19 pandemic when respirators were mainly available in one size designs. Given the minimal size variations of the one size products examined in our study, it is evident that achieving a change in the tight fit may not have been possible, even when trying out different models. This may not have been noticed because private users lacked the knowledge and professional equipment required for fit testing. In these exceptional epidemiological situations, where the population is affected and not just the workforce, there can be no one size respirator design, as it has been suggested by other authors before (Gakhal *et al.*, 2024).

Manufacturers of FFP respirators require information on anthropometric facial dimensions in order to design and produce products that will fit target group (Gakhal *et al.*, 2024). Facial dimensions typically used for respirator design are based on a bivariate model, consisting of measures of facial width (bizygomatic width) and facial length (menton-sellion length) (Lin & Chen, 2017; Zhuang *et al.*, 2007). Although these facial dimensions have been reported as important factors in determining whether a person passes or fails a fit test (Zhuang & Bradtmiller, 2005), other studies have questioned whether there is any consistent relationship between individual facial dimensions and respirator fit (Gross & Horstman, 1990). Taking into account the potential gender, ethnicity, age and BMI related variations in anthropometric facial dimensions, reported in the literature, correlations between individual anthropometric parameters and fit testing results seem rather unlikely (Chopra *et al.*, 2021; Spies *et al.*, 2011). In particular, the ethnic variability in facial anatomy that has been repeatedly reported in the literature suggests that caution should be exercised when using national RFTPs to test respirators designed for a different user population (Lin & Chen, 2017). In this context, it is understandable that the development of FFP2 respirators in Asia using American anthropometric data for European users could lead to problems with the tight fit of the products.

Under normal circumstances, an inadequate face seal poses a risk to the individual user. During the COVID-19 pandemic, when the concept of protecting others was also being pursued, an inadequate face seal also posed an additional risk to those around the respirator wearer. Had a wider range of products been available in different designs and sizes it is likely that the essential tight fit could have been achieved in the general population. According to a recently completed survey of respirator use during the COVID-19 pandemic in Germany (conducted by the German Federal Institute for Occupational Safety and Health), the majority of users hardly used any other products during the pandemic than the vertical flat-folded respirators examined in this study. Unlike these low-cost products, premium respirators use additional design features such as sealing lips, flexible areas and adjustable head straps to ensure a tight fit even for different face shapes. This may be why such products are often only available in only a few different generic sizes per model, if at all.

The high degree of intercorrelation between the length and surface data reported in the present study suggests that the size variations found in the respirators are an adaptation during the manufacturing process rather than an adaptation to the different human facial dimensions. The seal of a respirator is determined not only by the geometry and design of the mask, but also by the way in which it is secured to the wearer's head. The adjustable head strap, which has been used for many years in professional protective equipment, has probably given way to ear loops during the COVID-19 pandemic for reasons of material savings and cost reduction. Knobloch et al, investigating the fit of different types of respirators, found a 30% difference between vertical flat-folded respirators with head straps and those with ear loops, indicating that head straps were significantly better at achieving an adequate face seal (Knobloch *et al.*, 2023). Remarkably, none of the models we investigated in this study had adjustable head straps.

There are some limitations to this study. Firstly, we examined respirator dimensions and made theoretical conclusions about the resulting tight fit for different face types, but did not conduct any practical fit tests on subjects. We are well aware of the scientific controversy surrounding the significant relationship between respirator dimensions, facial dimensions, and successful fit testing. In this context, it is still unclear which dimensions should be considered for a meaningful description of the size gradations of respirators. In the present work, we have mainly considered the two-dimensional height, depth and total surface area of the products studied.

In contrast to the acute period of the COVID-19 pandemic, a relatively large number of retailers have stopped selling FFP2 respirators in these days. Although we tried to obtain a representative sample of respirators that were available on the market during the COVID-19 pandemic period, our sample may differ from the products available at that time. This is particularly true for generic size respirators, for which the current product range is very limited. The small number of these respirators, combined with the lack of standardized size specifications, results in large variations in the reported data within each generic size group. The size variations presented here have been determined using simple descriptive methods and can, of course, only be related to the corresponding complex three-dimensional facial structures of the human body to a very limited extent.

Further studies are needed to investigate the exact relationship between size gradations and tight fit in low-cost FFP2 masks. This could provide insights into how many size gradations are necessary in such products to reliably cover a wide range of face dimensions.

CONCLUSIONS

The COVID-19 pandemic has highlighted the inadequacies of the common one size design of low-cost, simple FFP2 respirators. Even professional users often found it difficult to achieve the required tight fit with such products, raising questions about the size range of the one size format, which is not defined by any European standard. This study examined the actual size range of one size FFP2 masks in relation to products with size specifications provided by the manufacturer. It was found that one size respirators show comparatively little variation in size in the upper third of the overall size spectrum, corresponding to size L (large). It is reasonable for manufacturers of FFP2 respirators to target the largest user group, adult male workers, but the resulting situation for other users is suboptimal if it is not apparent that these are primarily large to very large masks. Comprehensive and standardized information on the size of the products or, alternatively, on the intended user group is needed to facilitate the selection process for professional and private users in the future. This will require efforts from all stakeholders. Ergonomic research needs to collect up-to-date anthropometric facial data from relevant population groups, i.e., from young adults to the elderly and from different ethnic groups. Further research should be conducted on the relationship between BMI and facial anthropometric measurements in order to anticipate adjustments that may be necessary due to general future changes in population structure. Standardization bodies need to consider contemporary methods and current anthropometric data to provide manufacturers with specifications for the production of respirators and test houses with consistent and robust test methods for these products.

ACKNOWLEDGEMENTS

We would like to thank Lukas Hirschwald (AVT) for providing FFP2 respirators for our investigations.

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Informing the Public's Unassisted Use of Diverse Facepieces Designed to Form a Seal: Quantitative, Comparative Testing Using the ASTM F3502 Leakage Assessment Test Method

Chris Baglin[1*], Paul Baglin[1], Axel Bawor[1], Fiona Henriquez[2], William Mackay[3].

[1]tensARC, Ltd. Unit 122, Stirling Enterprise Park, FK7 7RP, United Kingdom +44 (0)7960 897809, [2]University of Strathclyde, [3]University of the West of Scotland
* Corresponding author email: Chris Baglin, chris.baglin@tensarc.com

ABSTRACT

Introduction: A National Academies of Science study details the need for respiratory protection for the public. However, assistance with facepiece selection, fit, and use, is rarely available in the community resulting in suboptimal use of facepieces. This study evaluated filtering facepiece respirators (FFR) and a barrier face covering in a setting where neither professional guidance nor assistance were available.

Objective: This study compares the effectiveness of various facepieces at blocking aerosols during unassisted use, using the ASTM F3502 Leakage Assessment—a modified version of the ASTM F3407 fit capability test.

Methods: An *ASTM F3502-2021 Standard Specification for Barrier Face Coverings* Leakage Assessment was conducted with a TSI PortaCount 8048, for facepiece models worn by participants given no coaching or assistance. The ASTM F3502 method follows *ASTM F3407 Standard Test Method for Respirator Fit Capability* but with modifications to account for unassisted facepiece use outside of a respiratory protection program. The performance target, a Leakage Ratio (LR) of 10, would reflect 90% blocking of particles. Two FFR models and a reusable barrier face covering in a tubular form were studied. There were 59 participants.

Results: The facepieces performed above the target performance level, indicating, on average, more than 90% protection. One FFR achieved 93% protection with a LR of 15.0 (SD=5.5%), another FFR achieved 92% protection with a LR of 12.2 (SD=12.6%), and the reusable tubular facepiece achieved 93% protection with a LR of 14.2 (SD=4.3%) after 110 laundering cycles.

Conclusion: Disposable respirators and reusable face coverings can be compared quantitatively using the Leakage Assessment test method in ASTM F3502, which provides a critical tool for understanding and improving unassisted use of facepieces by the public.

KEYWORDS: Unassisted, Leakage, Fit Capability; Product Test, Fit Test, Filtering Facepiece Respirator, Barrier Face Covering, Source Control, Reusable, Gaiter, Tubular

INTRODUCTION

There is a need for facepieces designed to protect individuals from inhalation hazards in the community and in unregulated workplaces (NAS, 2022), where use occurs without training or assistance. Studies of filtering facepiece respirators (FFR) and other facepieces indicate lower performance during unassisted use and, as a consequence, suggest a need to minimize risk to both naïve and expert wearers when no assistance is available (Hannum, 1996; Cummings, 2007; Lee, 2008; Oberg, 2008; Brosseau, 2010; Rembialowski, 2017; Yeung, 2020; Chen, 2022; Wang, 2024).

This study's aim was to test and compare the effectiveness of diverse facepieces in blocking aerosols during unassisted use. Two international consensus standards were the basis for the testing approach. *ASTM F3407, Standard Test Method for Respirator Fit Capability* (ASTM 2021a) has a product test method relating to facepiece fit. *ASTM F3502 Standard Specification for Barrier Face Coverings* (ASTM 2021b) adopts provisions of ASTM F3407, with some modifications designed to model unassisted donning. This study employed ASTM F3502'S Leakage Assessment plus relevant provisions of ASTM F3407, as directed by ASTM F3502. In contrast to facepiece fit testing, which assesses individuals in the workplace under a Respiratory Protection Program (RPP), these two methods evaluate a product's capability prior to its purchase and use. Performance levels developed by the National Institute of Occupational Safety and Health (NIOSH) help in the interpretation of product testing results.

Facepieces intended for unassisted use have requirements that are distinct from facepieces designed for occupational RPPs. For example, unassisted use relies on the wearer's recall of instructions (Chen, 2022; Yeung, 2020) as well as the wearer's intuition when they don an unfamiliar facepiece (Chasco, 2023). In RPPs, experts assist the wearer with facepiece selection and fitting, and workplaces implement environmental and administrative controls to manage risks. (OSHA 1998; Zhuang 2005; Zhuang, 2007; Zhuang, 2008; Zhuang, 2017; Chen, 2009; NIOSH, 2024). RPP controls also include intentional evaluations of technology to support RPP improvement (Chapman, 2024). RPPs drove development of methods for testing the fit capability of facepieces (Zhuang, 2017), resulting in ASTM F3407 (Coffey, 2021).

Section 1.1 of ASTM F3407 states its provisions apply to the testing of air-purifying, half-facepiece respirators, e.g., FFRs. The precise term for an ASTM F3407 fit capability test is "Respirator Fit Capability (RFC) test", which is defined in ASTM F3407. The term for the output of the RFC test is "subject RFC result", per section 3.1.6. Section 1.6 cautions that having the desired fit capability does not guarantee that (in subsequent fit testing under an RPP) a given wearer will be able to achieve the required "fit factor" when wearing a particular manufacturer's model. Fit testing focuses on finding the right facepiece model for a given wearer, as may be indicated by the fit factor achieved during fit testing (Regli, 2021). ASTM F3407 cautions that wearers "must always be given the opportunity to try other models or other manufacturers' respirators." ASTM F3407 is to be used in testing air-purifying, half-facepiece respirators. To help manufacturers address fit and leakage issues when developing other types of facepieces, ASTM F3502 adopted the ASTM F3407 test method by directly importing its terms, with some modifications.

In contrast to ASTM F3407, ASTM F3502 addresses the design, testing, manufacture, and supply of facepieces intended for unassisted use, such as in the community, where no training or fit testing is available. ASTM F3502 anticipates that manufacturer instructions will be the main form of assistance to the wearer, aided by product design. By comparison, during product testing under ASTM F3407, section 14.2, a test administrator can take the actions needed to achieve an optimal fit to an individual's face. Examples of such actions include familiarizing the wearer with donning, doffing, and seal check procedures; helping them to adjust the facepiece; re-explaining procedures after a failed seal check; and directing repositioning and repeat of the seal check. ASTM F3502's Leakage Assessment, while derived from ASTM F3407, anticipates the use of facepieces outside of RPP controls (Brosseau, 2022; Nicas, 2024; Brosseau, 2024).

ASTM F3502's section 8.3 describes its Leakage Assessment as a standard approach to assessing leakage through the entire facepiece, including the filter, face seal, seams, etc. According to Note 26 of the standard, Leakage Assessment is a "fit capability test" but is termed a "Leakage Assessment" to clarify its broader scope, which may include facepieces intended for use outside of a workplace, such as with children and general community use. In ASTM F3502, Leakage Assessment is optional, unlike filtration efficiency and breathing resistance testing, which are both required.

The Leakage Assessment output, a LR, has the same function as ASTM F3407's "subject RFC result" (the output from ASTM F3407's fit capability test). With respect to unassisted fit, ASTM F3502 section 8.3.5 directs that during the Leakage Assessment testing, "Test subjects shall don the barrier face covering sample without assistance from the test coordinator", and, "Test subjects shall receive donning and doffing training only from reading the user instructions or watching video versions of the instructions as provided by the manufacturer...". This direction can be contrasted with the high level of assistance and training that is available per section 14.2 of ASTM F3407.

While ASTM F3502 provides the Leakage Assessment as a test method for the fit of a facepiece, it does not set a minimum performance requirement for the resulting LR. NIOSH has articulated LRs of 5 and 10 as suitable for comparing the performance of ASTM F3502 barrier face coverings, whose presumed use is in unassisted settings. (CDC, 2024; Brosseau, 2022). By comparing LRs, wearers can gauge the suitability of a facepiece for use (e.g., in the community), when unassisted by the expertise and controls of an RPP.

METHOD

Ethics

Ethical approval for the project, inclusive of quantitative and qualitative studies, was granted by the University of the West of Scotland, School of Health and Life Sciences Ethics Committee (ref no:20956).

Performance target

An ASTM F3502 LR reflects the average of all results for all facepieces of a given size, per ASTM F3502 section 8.3. The objective is to determine the mean LR value for a given size facepiece.

ASTM F3502 does not articulate a LR performance level, but NIOSH has defined two performance levels which pertain to facepieces tested under the ASTM F3502 Leakage Assessment: Enhanced Performance, a level based on achievement of a LR of 5, and Enhanced Performance Plus, for a LR of 10 (CDC, 2024; Brosseau, 2022). For this study, NIOSH Enhanced Performance Plus (i.e., 10) was adopted as the mean LR target for each group of participants.

Table I presents the target and other LRs alongside the corresponding level of effectiveness in blocking particles, in terms of percentage blocked. The following discussion of the values presented helps explain the target performance level.

The ASTM F3502 LR is a non-linear function. An LR is equal to $\frac{1}{\%\ leakage}$, creating a non-linear hyperbolic function which has a vertical asymptote at zero leakage. To average the LR for a group of results, these values need to be converted back to a leakage percentage, a linear function. From these converted values, the average of the results can be calculated, which can then be converted back to a LR. The LR, percentage particles blocked, and the exposure level have the relationship depicted in Table I. Facepieces attaining the target LR of 10, would block at least 90% of particles, including particles that penetrate the filter and leak through all other sources. Use of a quantitative respiratory fit tester in N99 mode should measure penetration of all particle sizes within the range of the instrument (20 nm – 1 µm). This approach would provide a measure of Total Inward Leakage rather than a fit factor (which is designed to measure only particle leakage through the faceseal). In following the ASTM F3502 standard, the present study used this approach.

This approach is in contrast to ASTM F3407, in which the fit test mode is selected to ensure that only de-minimus penetration occurs through the filter element. Selecting a mode appropriate for a filter's presumed filtration efficiency enables focused attention on the faceseal rather than total particle penetration. For example, the filters for N95 and N99 FFRs capture test particles very effectively. As a result, developers of the ASTM F3407 methodology can assume that any particles measured occur from leakage (not filter penetration) and therefore are useable as an indicator of the level of fit.

ASTM F3502, was developed to test a wide range of facepieces with unknown filter types with widely variable abilities to withstand particle penetration. ASTM F3502 was also designed to extend to future innovations which may be developed to align with the standard's provisions. As such, ASTM F3502, through its Leakage Assessment provisions, seeks to measure all particles from all sources, providing an indication of a facepiece's as-worn performance. The exposure reduction and protection levels available from a facepiece model can be inferred from the degree of particle reduction achieved by the facepiece under unassisted use referencing the manufacturer instructions. A target of 10 aims for no more than 10% exposure to the wearer of the product, as anticipated under NIOSH Enhanced Performance Plus.

Table I. Chart depicting ASTM F3502 LR values and the degree of effectiveness they reflect in terms of percentage of particles

ASTM F3502 LR (Sample benchmarks at this level)	Percentage of particles blocked	Exposure level (all sources)
1	No particles blocked	Full exposure
2	50%	50%
5 (NIOSH Enhanced Performance)	80%	20%
10 (NIOSH Enhanced Performance Plus)	90%	10%
15+ (FFP2)	Minimum 93%	Maximum 7%
17+ (N95)	Minimum 94%	Maximum 6%
20	95%	5%
50	98%	2%
100	99%	1%

Note: *The LR and percentage values in Table I are presented to enable comparisons. In addition to different LRs, it provides information on the corresponding degree of effectiveness that these LRs would reflect, in terms of percentage of particles blocked. LRs of 5 and 10 reflect enhanced performance levels for fit (CDC, 2024; Brosseau, 2022) adopted in a NIOSH framework. LR values of 15 to 20 approach the exposure reduction capability of FFRs sometimes used in the community, such as FFP2s and N95 respirators. A LR value of 50, while notional here and not found in an existing framework, derives from work by other investigators on respirators for public health uses (FDA 2007). Finally, 100 is the ASTM 3407 fit capability performance level for facepieces, e.g., FFRs, designed for use in a Respiratory Protection Program (when the test is set up to ensure filter penetration is negligible). It bears repeating that the ASTM F3502 Leakage Assessment test method uses N99 mode, and therefore the percentage particles blocked encompasses all forms of leakage including leakage through seams, at the face seal, and by filter penetration. It is also worth noting that filter penetration testing, reported in percent efficiency, uses constant air flows, to model breathing, at rates which are higher than those typically achieved by a study participant carrying out exercises under a Respiratory Protection Program fit test. The values for the FFP2 and N95 benchmarks account for edge leakage (1%) and filter penetration (5%), hence the 1% lower benchmark (94%) for an N95 FFR.*

Selection of facepieces for study

Three facepiece models were chosen (Table II). Two models were FFRs certified to FFP2 under EN149, and therefore tested previously to a 94% filtration efficiency: 3M 8810, a cup shaped FFR, and 3M Aura 9320+ a tri-fold FFR. Both FFR models have two head straps, a "one-size-fits-most" design, and reported results for respirator fit-testing (Berger, 2022; Manninen, 1988; Williams, 2023a; Zhang, 2023; Derwein, 2024). Two versions of a tubular facepiece model (facegaiter, manufactured by tensARC, Stirling, UK) were used. Both are available in four sizes: Small (S), Medium (M), Large (L), and Extra-Large (XL). One version has a warp knit polyester fleece filter ("Filter A") and the other a non-woven polypropylene microfiber filter ("Filter B"). Each participant wore the Filter B version in two conditions: one sample was laundered once, the condition for first wear; the other sample had been laundered at least 110 times. As reported previously (Baglin, 2022), the tubular facepiece with Filter B performs at ASTM F3502's highest performance level for breathing resistance (<50pa; 5 mm H_20) and exceeds ASTM F3502's highest performance level for filter efficiency (50%), achieving 94% reduction in particle concentration.

Table II. All facepieces tested in this study.

Facepiece information					
Type	**Filtering Facepiece Respirator (FFR)**		**Reusable tubular facepiece**		
Model (Version and/or SizeTs)	3M 8810 (one size fits most)	3M Aura 9320+ (one size fits most)	facegaiter (Filter A version / Sizes S, M, L, XL)	facegaiter (Filter B version / Sizes S, M, L, XL	
Condition when tested	New in package	New in package	Laundered once (as at first wearing)	Laundered once (as at first wearing)	Laundered a minimum of 110 times

Note: *All facepieces were tested, as required (per the manufacturer), in their condition at first wearing by ASTM F3502 7.3.2.1. Also, ASTM F3502 7.3.2 and 8.3.2 require further testing, after the maximum number of launderings indicated by the manufacturer for a given performance level. The manufacturer's instructions for the reusable tubular facepiece direct the wearer to launder the facepiece before the first wearing; and the two versions of the tubular facepiece were tested after one laundering. Only the tubular facepiece with Filter B, however, was laundered further and tested in the resulting condition after 110 launderings. For the FFRs, their condition was only as found when new and in their packaging.*

Instrumentation selection and proficiency

The instrumentation selected for performing the ASTM F3502 Leakage Assessment test protocols was the TSI PortaCount 8048 (Grinshpun, 2020). This model calibrates automatically at the session start. One team member was trained and certified by Fit2Fit (Hempstead, UK) as a fit-test administrator (Baxter, 2024) in the month prior to data collection. This individual fulfilled the role of "test administrator" under ASTM F3407 and "test coordinator" under ASTM F3502.

Target participants

The target number of participants was 60, and the desired profile was educated individuals who were non-expert and/or "naïve" as to fit-testing.

The study's source of volunteers were students and staff at two campuses of the University of the West of Scotland, School of Health & Life Sciences. Potential volunteers were recruited through university-wide electronic notices and posters, by in-person visits to classrooms, and through one-on-one conversations at each of two campuses. Some participants were offered a £10 Amazon gift card by way of compensation, after amendment of the Ethics protocol.

Some considerations in establishing the sample size included the following. The study sought participants who would wear (a) at least one "one size fits most" FFP model and (b) one of four sizes of the tubular product, in at least one version in two conditions. As noted, the tubular product conditions reflected two reprocessed states, 1 or 110+ launderings. The provisions of ASTM 3502's Leakage Assessment require testing 10 participants for each facepiece size of a given model. While the FFP models had one size, the tubular product's four sizes required a participant count of at least 40 (10 participants x 4 sizes). Participants were not sized prior to attendance, and given the risk of cancellations by prospective participants, 50% more than 40 were estimated as needed, so a target of 60 participants was set.

The study design could not rely entirely on methodologies found in the respirator and FFR literature. The single head dimension which sizes the tubular facepiece is not among the measurements commonly employed in anthropometric studies. It would not be represented in any bivariate panel established (consistent with existing rules and protocols) to assess FFRs. As a result, recruitment strategies were important to the study. When conducting study recruitment in-person, the research team's health sciences lead, in some instances (to identify prospective participants who may size as a Large or Extra Large), made a subjective and non-invasive observational assessment of the prospective participant.

Preparation

Participants were told that they would need to refrain from smoking, eating, or drinking within one hour of their Leakage Assessment appointment. The tubular facepiece's manufacturer instructions recommend use of clothing that maintains its "tuck-in neck seal" when bending over. Therefore, participants were asked to wear to their appointment a high neck top, such as a crew neck t-shirt; sweatshirts were available for use by a participant with a top that was not suitable. There was no requirement to be cleanshaven. Cleanshaven wearers cannot be presumed in the community, so ASTM F3502 provisions do not mitigate facial hair's risk to the seal in its protocols.

On a test day, one of the two FFR models was randomly assigned to the day's participants.

A laptop was provided in the test area, enabling the participant to view the video instructions for the cup model FFR, the tri-fold model FFR and the tubular facepiece. The written instructions for each were also provided.

Consent

At their Leakage Assessment appointment, the participant read and signed a consent form permitting use of their data as needed for the project, subject to university requirements and the General Data Protection Regulation (GDPR) as instituted in the UK.

Data collection from research participants

Each appointment was 90 minutes in length, of which 20-30 minutes was devoted to collection of personal data from research participants. After consent was confirmed but prior to the Leakage Assessments, the test administrator created an ID number and Participant Profile, which recorded the exclusionary data, demographic data, including the presence of facial hair, prior FFR use, and sex (selected as either "male" or "female"). Anthropometric data were collected from the participant and recorded. In addition to face width and face length, required for ASTM F3502 and ASTM F3407, the following were measured: jaw width; nose length; nose protrusion; lip length; head circumference; and neck circumference. Images were taken to later approximate face depth and the nose gap area. Also taken was the measurement used to size a facegaiter: tubular facepiece seal circumference.

Conduct of a Leakage Assessment for each facepiece model

Data collection on the facepieces, employing ASTM F3502 the Leakage Assessment test method, typically ran 60 minutes per participant, within the 90-minute appointment. All Leakage Assessment tests were sequential, with only one participant tested at a time. Because the tubular facepiece was reusable, it needed to be tested in two conditions, as first worn (laundered once) and after the maximum number of launderings claimed by the manufacturer. The first facepiece to be tested was an FFR, randomly assigned in similar numbers. The participant was asked to sit at the laptop with the written and video instructions for the FFR to be tested. The participant was asked to study its instructions before donning the facepiece and following the seal check specified by the manufacturer. Per ASTM F3502, neither the test administrator, nor any other study team member, answered questions arising from a facepiece model's instructions nor assisted participants as they donned a facepiece. Testing different versions of the same product with the same participant did not require an additional review of wearer instructions.

The exercises performed by the participant were those required by ASTM F3502 (listed in ASTM F3407 section 14.2.7): normal breathing; deep breathing, turning head side to side; moving head up and down; talking; grimace; bending over; normal breathing. Each is performed for one minute, with the exception of the grimace, which is performed for 15 seconds. At the end of the test, the test administrator would review the PortaCount 8048 result. Per provisions of the standard, if the test administrator thought the results were low and the facepiece poorly fitted, the test administrator could request the participant to review the instructions and repeat the test once using the same protocol.

The study design permitted testing two FFRs for each participant, in addition to the multiple versions of the reusable tubular facepiece before and after extensive laundering. At the start of data collection, after seven instances of conducting Leakage Assessments on both FFR models (along with the other data collection), it was determined that testing two FFRs in an appointment was too demanding on the participant inside the 90-minute time limit.

For each participant all FFR testing was completed before the tubular facepiece testing began. For the tubular facepiece, the same manufacturer instructions applied to Filter A and Filter B models, so as noted the instructions were studied only once. The correct tubular facepiece size was supplied based on the tubular facepiece seal circumference, which is a facial dimension listed among the others noted in the subsection entitled “Data collection from research participants.” The participant then carried out further adjustment following the written and video instructions. When a participant had finished reviewing the written and video instructions for the tubular facepiece, as with the FFR, the test administrator observed but did not assist in donning nor in the seal check. Once the participant donned the model, completed the seal check, and said they were ready to proceed, the testing started.

Each participant was provided first with a Filter B model which had one laundering cycle. The same procedure was then repeated for the Filter B tubular facepiece with at least 110 laundering cycles. In some instances, the tubular facepiece subsequently was reprocessed, consistent with its instructions and prior study findings (Mackay, 2025), and used with a later participant. When time permitted, the same procedure was repeated for a Filter A tubular facepiece which had been put through a single laundering cycle.

Calculation of the LR for each facepiece

Under a ASTM F3407 RFC, individual exercises with a particular respirator are averaged using the harmonic mean, as carried out by the PortaCount equipment. Under ASTM F3502, even as informed by the ASTM F3407 provisions which it adopts, there are no explicit instructions to use the arithmetic or harmonic mean. Use of the arithmetic mean could create a bias wherein high performing individuals (outliers) within the group cause a significant increase in the result for the group. Under the study method, both the arithmetic and harmonic means were calculated to understand the extent of this bias.

RESULTS

Data were analyzed and visualized using Microsoft Excel (Redmond, Washington, USA). The analysis produced descriptive statistics, which are presented here, and inferential statistics to be reported in the future.

Participant data

There were 59 participants, of which 55 completed testing of the reusable, Filter B tubular facepiece and at least one FFR. For the reusable tubular facepiece version with Filter B, these 55 participants were tested twice, once wearing a sample of a version laundered a single time and once wearing a sample of a version laundered 110 or more times, as described in Table II. Given time constraints, a smaller number of participants, 27, were tested wearing the tubular facepiece with Filter A after one laundering cycle. Of 37 females, 35 completed testing and comprised 63.6% of the 55 participants. Participants ages ranged from 19-66.

Facepiece data, including LRs

The results for particles blocked for all participants, for each facepiece model, are shown in Figure 1 including the low performance outliers. The FFRs had wider ranges of results, while the tubular facepiece had narrower ranges, suggesting more consistency in values across participants.

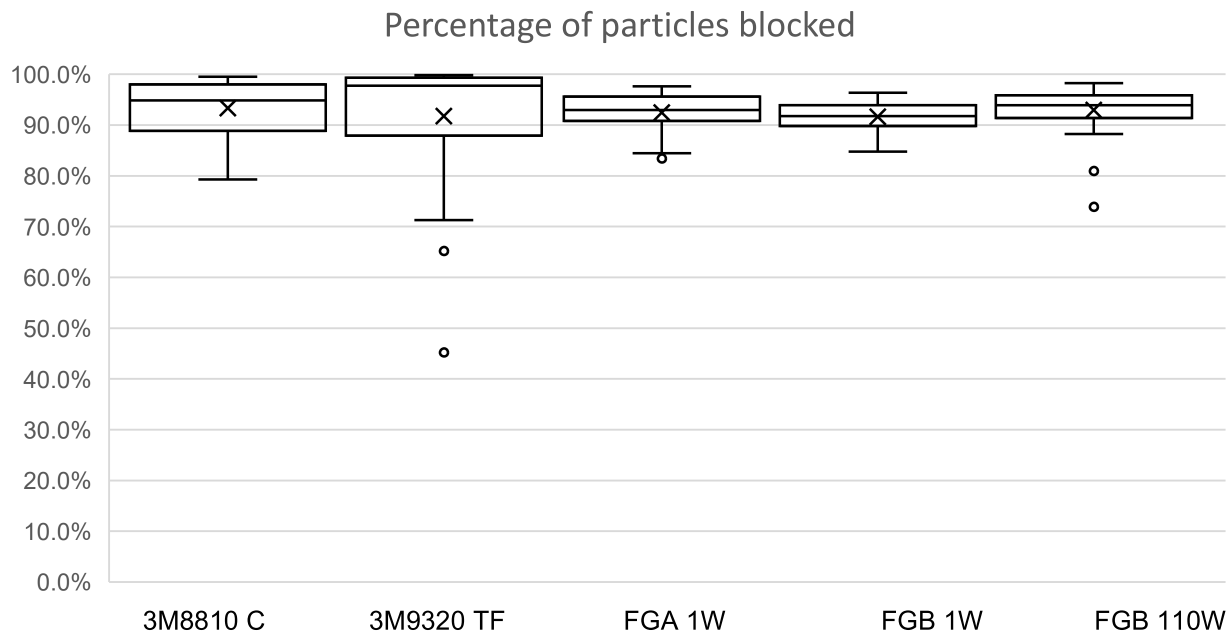

Figure 1. Percentage particles blocked based on LR value, by facepiece. ***Note:*** *Tests were conducted on four versions of three facepiece models, with one version having two conditions based on the number times laundered: FFR - 3M 8810 cup-shaped (3M8810C); FFR - 3M 9320 tri-fold (3M 9320TF); reusable tubular facepiece - facegaiter Filter A with one laundering (FGA1W); reusable tubular facepiece - facegaiter Filter B with one-laundering (FGB1W); reusable tubular facepiece - facegaiter Filter B with 110 or more launderings (FGB110W). In the box plot, the box represents upper and lower quartile, box line is median, the cross is mean, and the individual points are outliers.*

For each facepiece model, the average LR results exceeded the target performance level of 10, indicating more than 90% blocking of particles during typical conditions of wear. Table III presents each facepiece's Leakage Assessment results. The reusable tubular facepiece model referred to as the Filter B tubular facepiece was tested in two conditions, therefore results for both are presented.

Table III includes calculations of the average LR (for each facepiece version) by arithmetic mean. The results of the tri-fold respirator illustrate the difference between arithmetic mean and harmonic mean calculations: its LR was 94.3 by the arithmetic mean, and 12.2 by the harmonic mean. The tubular facepiece had the highest percentage of participants achieving the target and therefore the greatest consistency in results.

Table III. ASTM F3502 Leakage Assessment results reported as LRs.

Results by facepiece and their LRs for individuals tested	**N =**	**Average LR calculated by arithmetic mean**	**Average % of particles blocked (Standard deviation)**	**Average LR calculated by harmonic mean**	**% of participants achieving ≥10 LR (target level)**
3M 8810 Half facepiece (cup)	32	38.4	93% (5.5%)	15.0	75%
3M 9320+ Half facepiece (tri-fold)	34	94.3	92% (12.6%)	12.2	74%
facegaiter Filter A after 1 wash	27	16.6	92% (3.6%)	13.2	81%
facegaiter Filter B after 1 wash	55	13.5	92% (2.8%)	12.0	80%
facegaiter Filter B after 110 washes	55	18.9	93% (4.3%)	14.2	89%

Table IV presents information on participants with self-reported facial hair and the LR for the facepieces they wore during testing. The results for the cup model FFR indicate superior performance over the tri-fold model. The results for the tubular facepiece Filter B in the 110 laundering condition indicate it was the most consistent, with 12 of the 13 participants achieving the target level. Note that the sample sizes for Filter A and the tri-fold were smaller, and the results may be different if tested on a larger group.

Table IV. ASTM F3502 Leakage Assessment results reported as LRs, for facepieces worn by male participants with facial hair (self-reported stubble or beard). Sample size may not be representative of the adult male population.

Results by facepiece and their LRs for individuals with facial hair (stubble or beard) tested	**N =**	**Average LR calculated by arithmetic mean**	**Average % of particles blocked (Standard deviation)**	**Average LR calculated by harmonic mean**	**% of participants achieving ≥10 LR (Target level)**
3M 8810 Half facepiece (cup)	11	51.9	95% (5.2%)	20	82%
3M 9320+ Half facepiece (tri-fold)	5	26.6	85% (13.1%)	6.8	40%
facegaiter Filter A after 1 wash	5	10	90% (2%)	9.8	60%
facegaiter Filter B after 1 wash	13	12.6	92% (1.9%)	11.9	85%
facegaiter Filter B after 110 washes	13	14.7	91% (5.7%)	11.4	92%

Figure 2 presents the distribution, by facepiece type, of LRs within specific ranges, or bands, of performance. It provides a comparative view of their propensity to leak and their effectiveness in blocking particles under the test conditions. For all Leakage Assessments run, 97.5% resulted in a LR of more than 5. The most common LR was between 10 and 20.

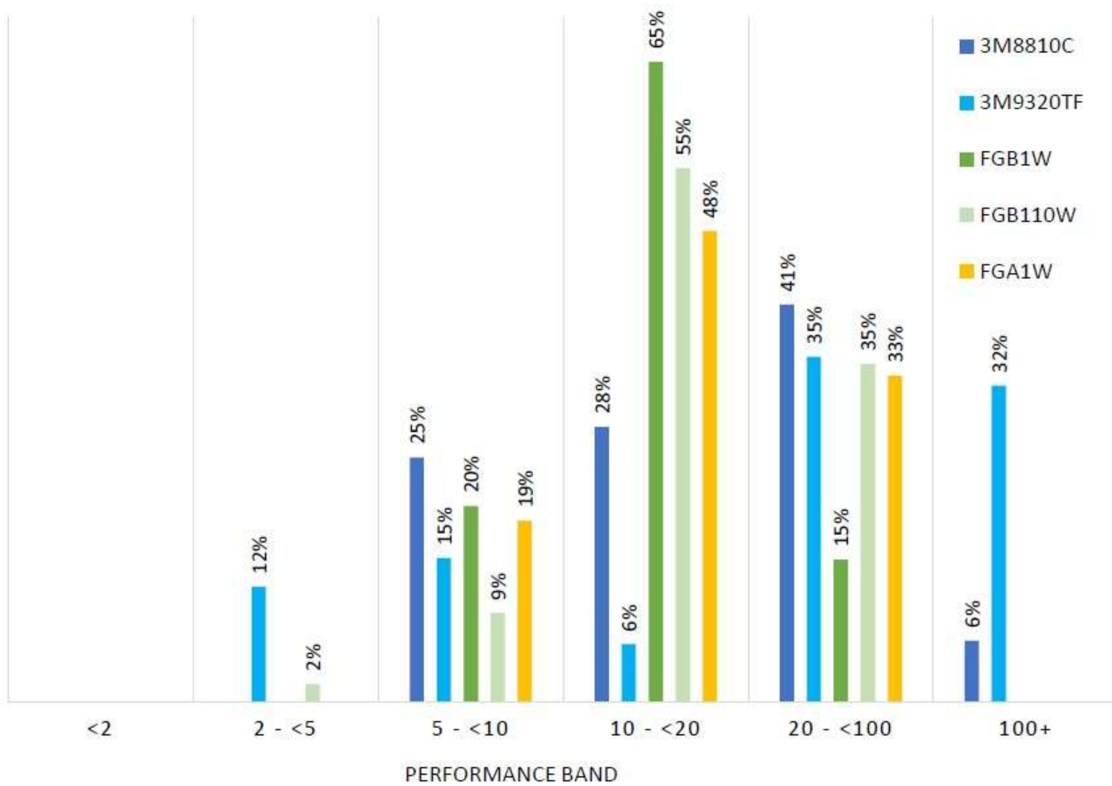

Figure 2. ASTM F3502 Leakage Assessment results, reported as LRs presented in a distribution by performance bands. ***Note:*** *Leakage Assessment results are presented by facepiece LRs collated into performance bands. See Figure 1 key for full names of facepieces.*

Figure 3 provides a cumulative view of each model's performance, by the percentage achieving the minimum LR specified, i.e., at or above 2, 5, 10, 20, or 100. The FFRs achieved the study target of 10 (or more) at a percentage of 75% of participants (24 of 32) for the cup shape and 74% for the tri-fold (25 of 34). Similarly, 80% of participants (44 of 55) wearing the Filter B tubular facepiece with one laundering met the target, while 89% of participants (49 of 55) wearing the 110-wash Filter B tubular facepiece met the target. For the band meeting or exceeding a LR value of 5, the lowest performing facepiece was the tri-fold FFR, yet this facepiece was also the highest performer with respect to achieving average LRs of 20 (or more) and 100 (or more).

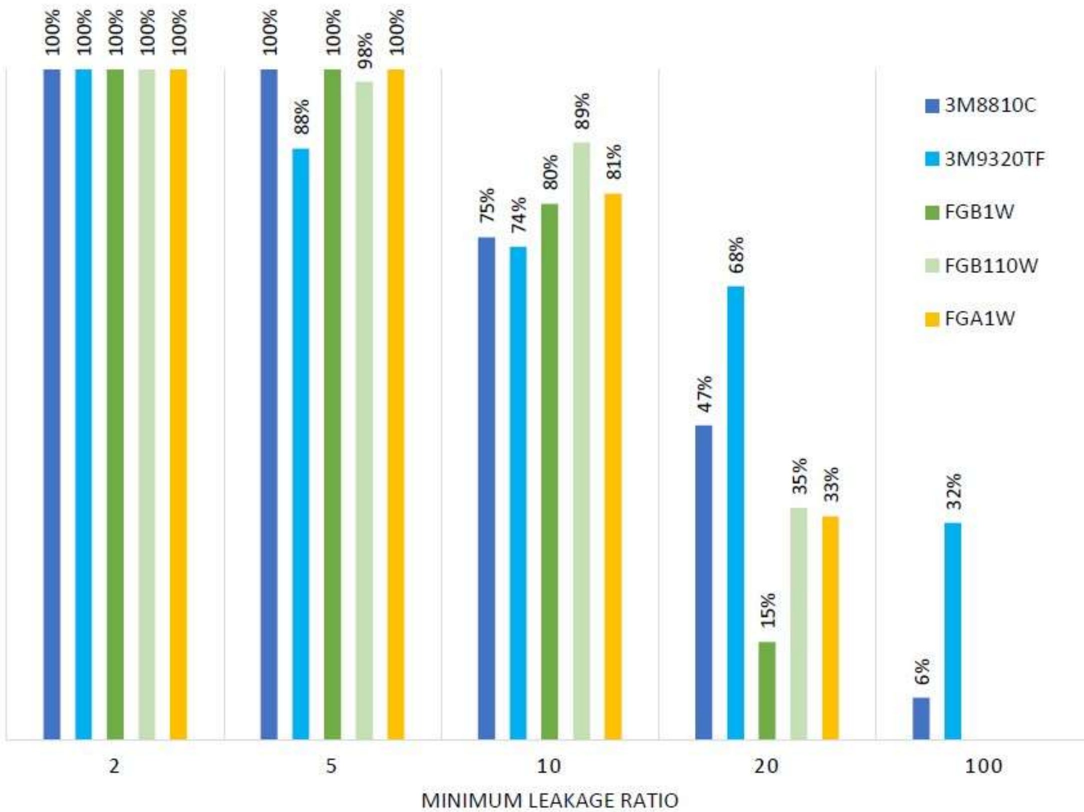

Figure 3. ASTM F3502 Leakage Assessment results showing the percentage of participants achieving LRs at or above 2, 5, 10, 20, or 100. ***Note:*** *This cumulative view indicates the percentage of the facepieces achieving a LR of 2 or more, 5 or more, 10 or more, 20 or more, and 100 or more. For example, a facepiece achieving a performance level of 20 will be counted in each of the set of bars labelled "2+", "5+", "10+", and "20+" but not further. See Figure 1 key for full names of facepieces.*

Figure 4 presents data for the reusable tubular product with Filter B, for samples worn after a single laundering, per instructions for first wear, and after at least 110 launderings. The LR increases by an average of 5 with most participants' LR seeing an improvement, as indicated by the number of values above the dotted line. The nonlinear nature of the LR means the increase will have a larger impact on the lower end of performance outcomes. For example, a LR of 5 which increases by 5 to 10, moves from blocking 80% to blocking 90%, while a LR of 15 which increases by 5 to 20, improves from 93.3% to 95%.

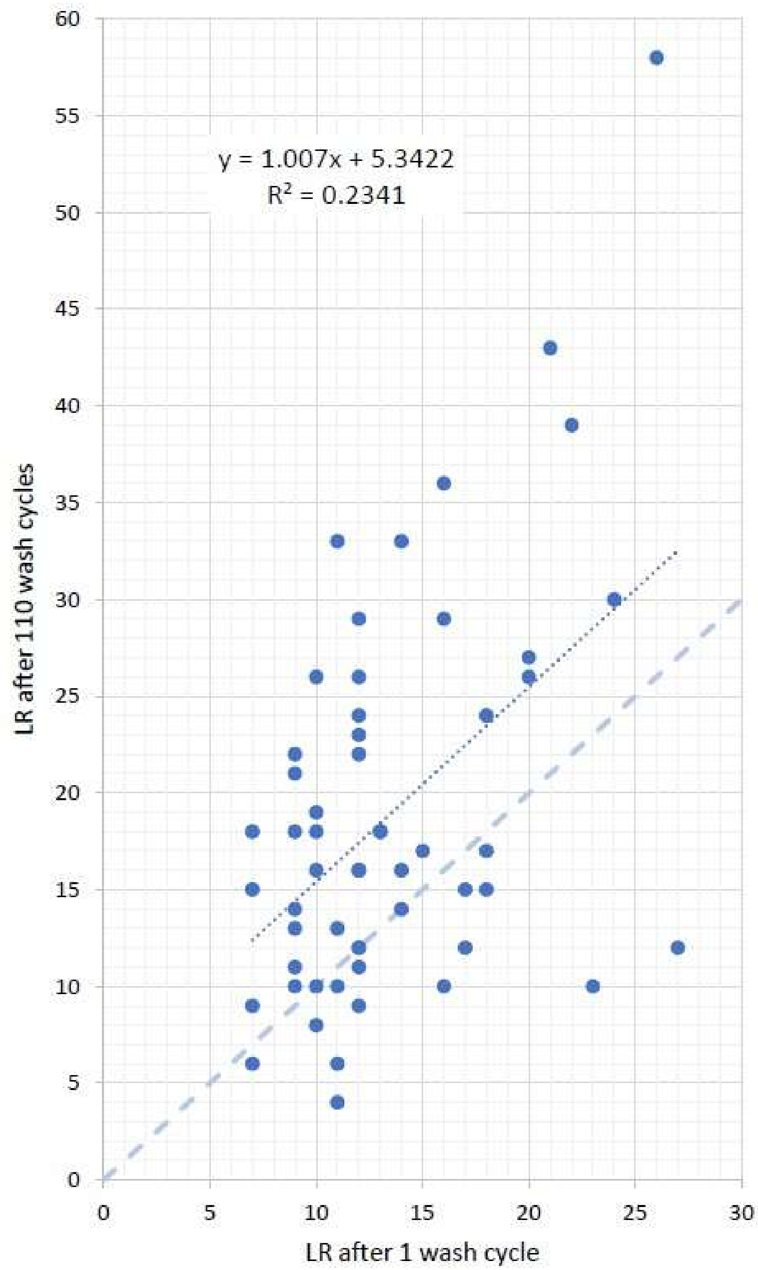

Figure 4. Comparison of LR after 110 wash cycles vs. 1 wash cycle for the reusable tubular facepiece with Filter B. ***Note:*** *This graph depicts leakage for the reusable tubular facepiece with Filter B, as indicated by the LR, with a higher LR value indicating less leakage. The LRs for individual participants (n=55) are each represented by a blue dot. The dashed line represents a theoretical equal performance before and after 110 launderings. The dotted line indicates the average change in performance, showing an overall improvement in performance after repeated laundering cycles. Actual values above the dashed line show improved performance after extensive laundering, while the values below the dashed line show decreased performance; some of the changes would be due to variability in donning. Samples tested after 1 laundering and after 110 or more launderings were not the same samples.*

Cross-tabulation of dimensions for bivariant panel and tubular facepiece sizing

To aid in improving fit, reducing leaks, and mitigating exposure to hazards, FFRs have been studied to determine key facial dimensions, but tubular facepieces have not. The following is a brief analysis of the anthropometric measurements taken in this study and test method outcomes. Analysis can identify trends in the relationship between the tubular facepiece and the two commonly required measurements, face length and face width. The relationship between individual results and individual facial dimensions will be explored in a follow-on paper.

Figure 5 plots the results for the facegaiter sizing dimension – the tubular facepiece seal circumference - for all participants against the bivariant panel dimension, face length. This plotting depicts the relationship between these two dimensions. As seen, there is a weak correlation between the tubular facepiece size and face length. There is a slightly stronger but still fairly weak correlation between the tubular facepiece size and face width, as seen in Figure 6. The lack of a clear relationship has implications for sizing. Sizing seeks to predict the most suitable facepiece for the wearer prior to its selection and acquisition. Outside of an occupational setting, there is very likely no fit testing system in place for the wearer. In this study, the tubular facepiece designed for unassisted settings performed well compared with half facepiece FFRs designed for assisted settings. However, it must be asked whether current dimensions (face length and face width) can be used to predict sizing and fit sufficiently for tubular solutions, as currently required under ASTM F3502.

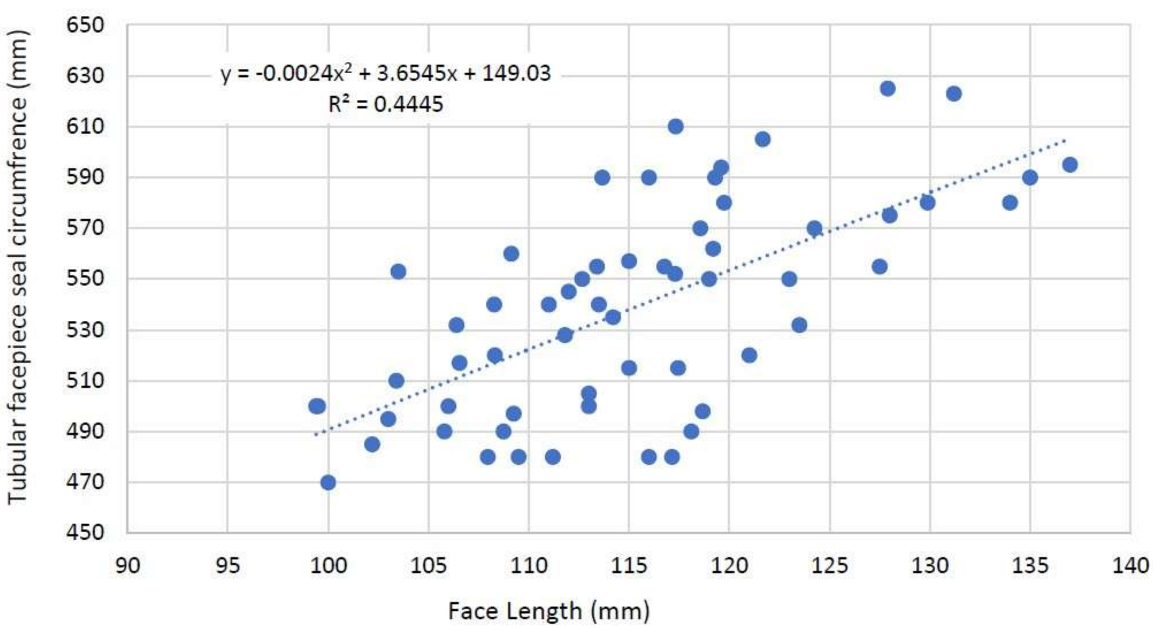

Figure 5. The relationship between participant face length and tubular facepiece seal circumference. ***Note:*** *The data in this graph reflect measurements of facial dimensions from all 59 study participants. Face length is a required measurement under ASTM F3407, and therefore required under the ASTM F3502 section 8.3 Leakage Assessment. The tubular facepiece seal circumference is the anthropometric measurement used in this study for sizing the tubular facepiece, as directed in the manufacturer instructions of the model chosen for study.*

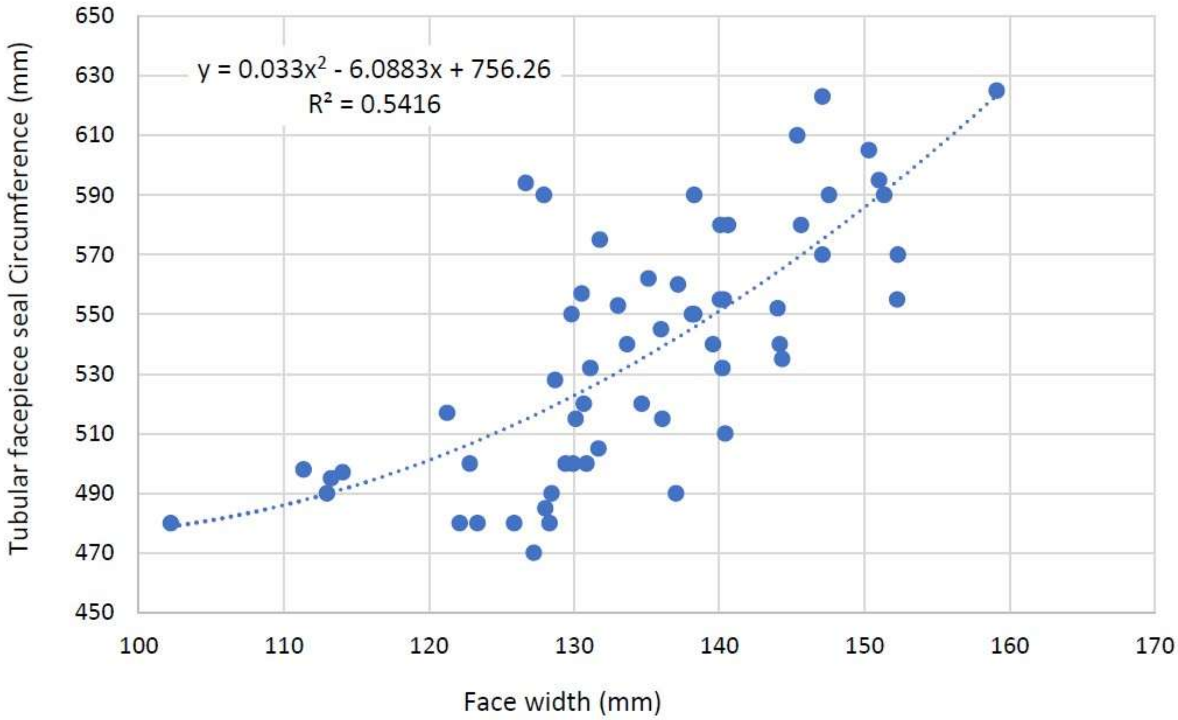

Figure 6. The relationship between participant face width and tubular facepiece seal circumference. ***Note:*** *The data in this graph reflect measurements of facial dimensions from all 59 study participants. Face width is a required measurement under ASTM F3407, and therefore under ASTM F3502 section 8.3 Leakage Assessment. The tubular facepiece seal circumference is the anthropometric measurement used in this study for sizing the tubular facepiece, as directed in the manufacturer instructions of the model chosen for study.*

DISCUSSION

Without assistance and by following only the supplied user instructions, wearers of the tested facepiece models achieved the NIOSH Enhanced Performance Plus requirement: a LR of ≥10. While some individuals achieved LRs below 10, the average LR for all wearers wearing a given facepiece exceeded 10, meaning that each group (wearing a given facepiece) was protected from at least 90% of all particles. Table III provides details. On average, one version of the reusable tubular facepiece blocked 93%, while a cup FFR was at 93% and a tri-fold FFR was at 92%. Also, for the cup FFR and the tubular facepiece, facial hair was not an obstacle to achieving the target performance level, as was seen in Table IV. The ASTM F3502 Leakage Assessment helps illustrate the quality of reusable, alternative facepieces. It also suggests potential use as a tool to determine which facepieces are suitable for a given setting. Facepiece alternatives could be tested, including a NIOSH-certified N95; an “international" FFR such as FFP, KF94 or KN95 respirators certified under other country’s standards (CDC, 2022); a “Wildland Firefighting and Urban Interface Firefighting Protective Face Covering” (NFPA, 2025); or a ASTM F3502 Barrier Face Covering. Using ASTM F3502’s Leakage Assessment, these facepieces can be assessed with some rigor before wider distribution in the community. Facepieces could be assessed for possible use in unregulated workplaces (Dosman, 2000; Geng, 2024; NAS, 2022); in workplaces seeking to address wearer preferences (Aggarwal) such as mitigating the impacts of facial hair (Williams 2023b; Bhatia, 2022; Jung, 2023); or in the community (NAS, 2022).

Below are issues for consideration when adopting the use of a ASTM F3502 Leakage Assessment in product development, and in refining ASTM F3502 further.

Reporting of Facepiece Performance

Consideration should be given to confirming the intent to use the harmonic mean in reporting results under the ASTM F3502 Leakage Assessment. ASTM F3502 section 8.3.6 states that, for each size, one must report a calculation of the average LR. This calculation is for all bivariate panel cells for the stated product size (in the modified NIOSH bivariate panel used under ASTM F3502). Unlike ASTM F3407, ASTM F3502 does not specify what is meant by “average”, the arithmetic mean or harmonic mean; however, the term “average” will typically refer to the arithmetic mean. The ASTM F3502 LR and the ASTM F3407 RFC (Respirator Fit Capability) both describe non-linear relationships. Using the arithmetic mean will introduce an error when there are high performing outliers, which increase the reported average value incorrectly. This shift can be substantial, as seen in the results for the two FFR models in Table III. Using the harmonic mean allows the results for each wearer to be converted back to a value on a linear scale, averaged, then converted back to the correct LR for the group. This is the method used by ASTM F3407 in summing the individual results from each exercise in order to calculate the RFC for the individual. It is also the method used internally by the TSI PortaCount 8048. Use of the harmonic mean is particularly important where there may be a wide range of results in testing facepiece fit (Brown,1992, Brown, 1995). ASTM F3502 should be revised to specify in explicit terms, and with appropriate qualifications, that the LR is to be calculated using the “harmonic mean.”

It also may be helpful to consider whether use of the harmonic mean itself is the most suitable approach for evaluating results from individual test subjects. A mean can signify that less than 50% of the test participants achieved the stated performance value. That outcome may be sufficient for testing respirators under ASTM F3407 (whose pass mark is 13 out of 25 participants wearing the product) because such respirators are designed for use in an RPP which also conducts individual fit testing on its participants. Specifically, an individual fit test determines which facepiece, among a range of possible products, meets the requirements and is suitable for the individual wearing it. However, there are situations outside of a regulated or RPP setting where an individual requires protection and could be largely reliant on the manufacturer’s product capability test. Because such cases are foreseeable, it may be more appropriate to require that a large majority of fit capability test participants achieve the required performance level. An increased number or percentage performing as desired would suggest that the assessment more accurately represents wearer expectations. The results from Table III show that the products tested in this study achieved a pass mark of between 74% and 89% for a LR of 10. For a target LR of 5, 97.5% of test participants achieved this. Based on these findings, it might be reasonable to add a requirement that at least 75% or 80% of test participants meet a designated performance level.

Notably, the performance of the tubular facepiece product was not substantially influenced by face width or face length, which are the dimensions typically used in recommending a facepiece size to an individual. This finding and others will be reviewed in detail in a follow-up paper looking at the relative influence of anthropometric dimensions on fit as indicated by the ASTM F3502 LR.

Facepiece Fit Capability - Distinguishing Among Facepieces Designed for Unassisted Use.

Investigators use ASTM F3502 to compare the filtration and breathing resistance performance of diverse facepieces (Brochu, 2024; Hyun, 2023; Freeman, 2021). With respect to facepiece fit and overall protection performance when worn, ASTM F3502’s Leakage Assessment also could inform the public’s unassisted selection of various facepieces. A non-exhaustive list of key areas for review includes product types, anthropometric dimensions, and performance levels.

With respect to product type, ASTM F3502 does not restrict application of its test method to a particular facepiece type (e.g., half face design), thereby supporting innovation. As discussed, this study’s facepieces included the tubular form factor. Product design experts note the benefits of the tubular form for facepieces (Brandel, 2020; DuPuis, 2022; Comeau, 2024; Bartoszek 2020; Aherleroff 2021; Schmitt, 2022), as do studies (Cooper; Mueller) and other documentation of professional judgment (Bhattacharjee 2020; Bothra 2020; Comeau 2020). These sources assess the tubular form’s value to retention systems, leakage control, comfort, and other design parameters. ASTM F3502, sections 5.2.1 and 8.1.1.3, expressly anticipate a tubular form, permitting comparison to other facepiece types (Louie, 2022). However, studies which compare the tubular form typically examine off-the-shelf versions designed for sun or wind protection (Lindsley, 2021) or certain improvised configurations (Pan, 2021; Lindsley, 2021; Cooper, 1983; Mueller, 2020). Few have studied the tubular form when intentionally designed for use by the general public as respiratory protection. Historically, there has been changeable guidance (Freeman, 2021; Freeman, 2022) and confusion about this facepiece type (Doron, 2023). In Figure 3, the data showed FFRs afforded the highest levels of protection, when fitted well to an individual participant, whereas participants wearing a tubular facepiece achieved the target performance at a larger percentage than those wearing either of the FFRs.

Study findings about the reusable tubular facepiece include the following. Firstly, the tubular form compares well to FFRs, as seen in Tables III and IV and in Figures 2 and 3. Secondly, although its filter material has a lower filtration capability than the Filter B version of the tubular facepiece (Baglin, 2022) and the FFR models studied here, the Filter A version performed at a high level. As such, the Filter A tubular facepiece reflects one promise of the tubular form: a strong seal yet an exceptionally low breathing resistance (1.7 mm H_2O; 17 Pa) (Baglin, 2022). In this study it showed high performance as worn, due to low leakage and enhanced filter performance at the lower operational pressures associated with normal breathing.

Thirdly, fabric construction can be a benefit. In the Results section, Table III, the LR for the reusable tubular facepiece with Filter B is compared before and after 110 wash cycles, with higher performance with more laundering cycles. In Figure 4, LR values were higher in the more heavily laundered version (110+ laundry cycles). The initially stiff Filter B material softens during the first few laundering cycles. This softening changes the hand of the material such that the fabric follows the contours of the face more closely, resulting in an improved seal and reduced leakage.

Fourthly, the location of where the tubular facepiece seals to the face is less variable than for other styles, indicating that this form may provide Near Universal Fit. The seal avoids areas problematic for half-face designs. The tubular facepiece in this study provided a consistent level of performance across a wide range of individuals. Such consistency is advantageous in settings outside of an RPP. For unassisted settings, however, the potentially wide range of performance parameters and testing outcomes call for a complex framing that is challenging to communicate. Also, a fragmented approach to assessing tubular facepiece performance reinforces the observation that there is no widely accepted method (Grozkowska-Sobas, 2023).

The same issue arises when comparing the performance of alternative FFRs under unassisted use. For example, there is messaging in the community to use an “N95 or equivalent” but it is imprecise. KN95s have significantly more leakage than N95s (Duncan, 2021), partly due to ear loops (Caoili, 2020). However, there are examples of public health experts (Safarpour, 2022; Cahill, 2024; McGarity, 2024) treating KN95s and N95s as equal, even while CDC groups KN95s among “international” respirators which are certified under other countries’ rules (CDC, 2022). FFP2s and KF94s, certified to 94% filtration efficiency, routinely are equated with N95s, e.g., when distinguishing them from non-respirators (Lu, 2023; Tang, 2021; Dheda, 2021). However, KF94 fit issues produce more leakage than N95s (Park, 2021); and, where FFP2 models have ear loops, face seal leakage is more likely and they are much less effective (Baxter, 2024.). NIOSH has conducted extensive outreach to improve respirator use in the community, including a Respirator Fit Evaluation Challenge (Wehring, 2024) and Respirator Fit for All (Pollard, 2024). The aim of helping the public’s use could be supported by a common product test method to assess FFR performance, as worn under unassisted use, to better indicate the likely impact of different products as a personal or community wide intervention.

With respect to anthropometric dimensions, substantial scientific research, debate, and consensus (Zhuang, 2017) led to the adoption of two dimensions for sizing half face respirators: face length and face width. It is understood that the type of FFR (Manganyi, 2017; Fu, 2024) as well as the nose gap area (Griffin, 2024), nose protrusion (Khairul Hasni, 2023; Han, 2003), jaw width (Winski, 2019), and other features (Chopra, 2021; Manganyi, 2017) influence fit also. Unlike the half-face designs in the aforementioned studies, the tubular facepiece is not sized by those dimensions. Despite that, the tubular facepiece, tested under a ASTM F3502 Leakage Assessment in this study, performed well. Its results were comparable to an FFR’s. The tubular form’s performance also was more consistent than that of the FFRs, as seen in

Figure 1 and Table III, even after extensive laundering. This consistency suggests a more universal fit across participants by avoiding areas of the face to which it is more difficult to seal. For the tubular form, a sizing system based only on length and/or face width is not suitable and a new approach is required which more closely aligns to fitment requirements.

Finally, consideration might be given to ways to support the development of facepieces for unassisted use. There are several options.

One approach is the adoption of evidence-based performance levels. Table I provides a potential set of LRs for gauging performance. As noted in the Methods section, NIOSH has defined two performance levels for facepieces tested under the ASTM F3502 Leakage Assessment: Enhanced Performance, based on achievement of a LR of 5, and Enhanced Performance Plus, for a LR of 10 (CDC, 2024; Brosseau, 2022). Performance standards would aid the public in discerning between facepieces, including FFRs, for unassisted use. Adding the NIOSH values, 5 and 10, into ASTM F3502 would be an important step. Most LRs for all models in this study were between 10 and 20, reflecting 90% to 95% blocking capability. Employing higher performance levels may be challenging, however. Evidence from this study would suggest a lower level than 20. Specifically, less than half of the cup and tubular models exceeded 20, but more than two thirds (68%) of the tri-fold did exceed 20, reflecting 95% blocking. These results suggest a level of 20 might be difficult to achieve consistently. Notably, NIOSH did not adopt a level of 20 despite expert reviews and recommendations for doing so (Brosseau, 2022).

Another option would be to increase the percentage of participants which must meet a designated performance level in product testing for this design parameter. As noted, this study's data suggest that a 75% or 80% figure might be useful and overcome reliance on a mean. Consideration, however, must be given to the cost to manufacturers who seek to develop and test their innovations in this area. High costs could see the continued reliance on improvised solutions by the public. There are other ways to support the development of facepieces for unassisted use. These approaches include developing requirements for specific user populations and better tailoring user information, e.g., manufacturer instructions, to unassisted conditions. Study data on the latter topic will be reported in a follow-up paper.

All of these approaches are complementary and can strengthen the already high value of the ASTM F3502 Leakage Assessment.

CONCLUSION

ASTM F3502 helped standardize facepieces across a range of designs, quality, and performance. Under it, a reusable facepiece in a tubular form can demonstrate consistent, high-level, and sustained performance after repeated launderings, across a range of wearers and sizes. Also, ASTM F3502's test methods enable comparisons of product performance, across facepieces, outside of an RPP. In particular, it is possible to compare the performance of facepieces designed for occupational settings yet extended to unassisted use in the community (e.g., N95s and international respirators such as KN95s, FF94s, etc.) with facepieces intentionally designed for unassisted use outside of an RPP. Targeted changes to ASTM F3502 could enhance the standard for such purposes.

Limitations

Like some other particle-counting instruments, PortaCount 8048 is known to underreport particles within the facepiece. The reason is that it samples continuously during the full breathing cycle, rather than just during inhalation. Another limitation is that facial hair was self-reported; future studies could adopt an objective method (Floyd, 2018). Also, it was not possible to have the same participant use the same sample for each test. Two different sets of the reusable tubular facepiece with Filter B were laundered (for a different number of cycles) to test each condition in the same session on the same participant. Finally, recruitment occurred in a university setting which may not reflect the general population.

ACKNOWLEDGEMENTS

The Scottish Funding Council provided support. The authors wish to acknowledge and thank University of the West of Scotland colleagues Constantina Papadopoulou PhD and Fiona Smith PhD, MPH for their extensive contributions in managing participant recruitment and other logistics critical to this study. All views are solely those of the authors.

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Developing Regulatory Framework and Performance Criteria for Children's Respiratory Protective Devices – a White Paper

Jonathan Szalajda[1], Jessica Tredinnick-Higgins[2], Margaret Sietsema[2], Claire J. Horwell[3], Stephanie Holm[4], Stephanie Lynch[5], Simon Smith[6], Caroline Johnson[2]

1. JVS Respiratory Protection Consulting, LLC, Pittsburgh PA
2. Personal Safety Division, 3M Center, St. Paul, MN, US
3. Institute of Hazard, Risk & Resilience, Department of Earth Sciences, Durham University, UK
4. Stephanie Holm Consulting, Vancouver, BC, Canada
5. OHD, Birmingham, AL, US, and current President, International Society for Respiratory Protection (ISRP)
6. Retired, currently chair ISO and CSA Working Groups

Corresponding author: Jonathan Szalajda, JVS Respiratory Protection Consulting, LLC, 605 Moreland Drive, Pittsburgh, PA 15243: szalajda@verizon.net

ABSTRACT

This White Paper is a call to action for the development of a regulatory framework and performance criteria for children's respiratory protective devices. The unique physiological and developmental characteristics of children make them very susceptible to inhalation hazards. Almost all respiratory protective devices (RPDs) are designed for adult occupational use and rarely address the needs of pediatric populations. Studies in National Academies of Sciences, Engineering, and Medicine (NASEM) proceedings indicate that, while respirators can reduce children's exposures, they are generally less effective than when designed for, and properly used by, adults (NASEM, 2022). Challenges such as lower inspiratory and expiratory pressures, discomfort due to filtration (breathing) resistance, and cognitive limitations in younger children make respirator usage more complex. In addition, the facial dimensions vary greatly. These factors highlight the necessity for specialized design frameworks that ensure safety, usability, and accessibility (NASEM, 2022).

The International Society for Respiratory Protection (ISRP) has been a collaborating partner with the FACE-UP (Factors Affecting Childhood Exposures to Urban Particulates) project, which aimed to establish the efficacy of children's use of respiratory protection to reduce their exposure to particulate air pollution.

As part of this effort, ISRP and FACE-UP conducted two workshops in 2024 to give an overview of existing information and identify knowledge gaps surrounding respiratory protection for children. The intent of the workshops was to address priorities for the development of regulatory frameworks, including recommendations for design and performance criteria, the design of a global consensus standard, manufacturing and distribution considerations, product registration requirements, selection and use guidance, education and training, ethical considerations, and recommended next steps. This White Paper lays out these recommendations.

A worldwide standard for pediatric respirators should be established under the leadership of a global consensus standard development organization, such as the International Organization for Standardization (ISO) or ASTM International, ensuring adaptability to diverse populations and regional needs. This requires standardized testing protocols that incorporate child-specific physiological and ergonomic considerations; regional flexibility within global standards to account for variable demographics and cultures and environmental exposures, and alignment with existing national regulatory frameworks to streamline certification and adoption.

Developing pediatric RPDs necessitates a nuanced approach which integrates filtration, breathability, fit, comfort, and accessibility. By leveraging insights from recent research and establishing age-appropriate

performance standards, manufacturers can create effective solutions tailored to children's respiratory protection needs.

Additionally, there is a need for comprehensive regulatory frameworks, which include guidance for families on when, where, and how respirators should be used by children, including references to the worldwide consensus standard as part of clear selection guidance. Continued interdisciplinary collaboration will refine these guidelines and enhance protection for pediatric populations amid evolving health and safety challenges.

Keywords: pediatric respiratory protection; global consensus standards; respirator design and performance; air pollution exposure; child health vulnerability; filtration efficiency and fit; respirator regulatory frameworks

INTRODUCTION

There is a recognized need for an effective regulatory framework, including a global consensus standard, to be developed to help protect the respiratory health of children. There are currently discussions to develop such standards by the International Organization for Standardization (ISO) and ASTM International. This White Paper aims to guide that standard making process.

Children are particularly vulnerable to airborne hazards, including air pollution and infectious diseases. The World Health Organization (WHO, 2018) estimates that 93% of children under 15 years old live in areas with air pollution exceeding safe guidelines, contributing to 543,000 deaths in children under five due to respiratory illness in 2016 (WHO, 2018). Similarly, UNICEF reports that air pollution was the second leading risk factor for child mortality in 2021, accounting for 709,000 global deaths (UNICEF, 2021).

Higher respiratory rate, increased activity, and ongoing lung development make children more susceptible to airborne pollutants (NASEM, 2022). Their higher respiratory rate per kilogram of body mass increases exposure to airborne toxicants, while their higher activity levels and rapid craniofacial development before age 10 complicate proper respirator fit (NASEM, 2022). Holm (2022) underscores these factors, emphasizing that children inhale more air per kilogram of body weight than adults.

Short- and long-term health effects are a concern for children. Exposure to polluted air and respiratory pathogens increases the risk of infections and respiratory distress in children (EPA, 2019). Long-term exposure can impair lung development, contributing to chronic conditions such as asthma and cardiovascular disease (WHO, 2018).

It is essential for governments to prioritize the introduction and enforcement of policies aimed at reducing and ultimately eliminating air pollution, particularly emissions generated by combustion processes. While these systemic changes will take time to implement and achieve measurable results, it is of paramount importance to ensure that children grow into productive and healthy adults. In the interim, especially in regions with consistently poor air quality—such as densely populated cities or areas affected by agricultural burning and wildfires—personal protective measures have become a necessary and proactive mitigation strategy, rather than a last resort.

Regulatory frameworks will play a crucial role in shaping the pediatric respirator market by enforcing safety and performance standards and clarifying the circumstances in which pediatric respirators may be needed. These future regulations would drive demand for higher-quality, certified products and significantly influence manufacturer strategies. However, variations across regional regulatory systems create challenges for manufacturers seeking to operate globally.

The COVID-19 pandemic has increased public use of respiratory protection and boosted the production of certified respirators and non-certified facemasks (MacIntyre, 2025; OSHA, a; Toner 2021). During the pandemic, respirators emerged not only as personal protective equipment (PPE) but also were shown to be a source control product, capable of preventing respiratory droplets from escaping infected individuals and reducing the spread of airborne pathogens (MacIntrye, 2025). Unlike facemasks designed primarily for source control - for which standards are still evolving - respirators offer dual protection, shielding the wearer and mitigating the transmission of infectious agents to others. This functionality underscores the necessity to develop, for respirators and source control devices, their own distinct standards, tailored to their respective roles.

It is now more socially acceptable to use respiratory protection for reducing children's exposure to particulate air pollutants compared to before the pandemic (van der Westhuizen, 2020). However, due to the lack of design standards for pediatric respiratory protection, existing respirators are variably effective. This, and the need for further scientific evidence on their efficacy, has created a lack of trust in current products which has hindered governments and international humanitarian organizations from implementing policies or guidelines to protect children from air pollution through personal interventions (McDonald *et al.* 2020).

The International Society for Respiratory Protection (ISRP) is collaborating with the FACE-UP (Factors Affecting Childhood Exposures to Urban Particulates) project, which aims to reduce children's lifetime vulnerability to non-communicable diseases by minimizing exposure to particulate air pollution during childhood. FACE-UP is a research consortium funded by the UK Research and Innovation Global Challenges Research Fund Programme. It investigated factors affecting children's exposure to urban pollution and the efficacy of respiratory protection for children. The project examined the fit and filtration efficiency of children's respiratory protection, potential health benefits in various exposure scenarios, and behavioral, social, ethical, contextual, and policy drivers influencing its effectiveness and sustainability (Sleeuwenhoek, 2025; Gudgin Dickson, 2025). It also looked at community motivation, opportunity, and capability for behavior change required for successful uptake (FACE-UP, 2023).

As part of this initiative, ISRP and FACE-UP conducted two workshops, the first to give an overview of existing information, and the second to identify knowledge gaps related to children's respiratory protection. The goal was to prioritize information required for the development of global consensus standards for such protection, including recommendations on design and performance criteria, manufacturing and distribution considerations, education and training, ethical aspects, and future steps.

The first workshop was held online on 26 June 2024, and included keynote presentations on the state of knowledge on children's respiratory protection to the ISRP community, followed by a question and answer session and discussion (recording available: https://www.youtube.com/watch?v=IEUVRUfSqiM&t=10s). The second workshop took place on 26 September 2024, at the ISRP Conference in Oxford, UK. The workshop was open to all interested conference participants and included the keynote speakers from workshop 1. It involved round-table discussions that contributed to the outline of this White Paper. The table discussions focused on: 1) designing respirators for children; 2) development of design standards; and 3) supply chains, access, and affordability. Each table addressed pre-defined questions and topics (Appendix I), with five or six conference attendees per table, including a chair/rapporteur and one or two note takers (see Acknowledgements for attendees).

This White Paper follows on from the workshops and is a call for the development of global consensus performance standards and accompanying guidance on children's respiratory protection. It aims to offer recommendations and insights on key considerations for developing a global regulatory framework, including a consensus standard for respiratory protection for children exposed to environmental and public health hazards, including infectious particles and particulate pollution. The scope of this paper does not include child labor protections.

EXISTING INFORMATION AND DATA

Standards are guidelines developed by experts, offering best practices for performance, quality and safety. Establishing a global standard for pediatric respiratory protective devices (RPDs) is essential, as adherence to standardized criteria enhances product safety, interoperability, and overall system efficiency (ANSI, n.d.; ISO, 2021). Standards help to ensure that products are safe for their intended use, reliable, and compatible across markets. In an increasingly interconnected global marketplace, alignment with international standards benefits manufacturers, developers, distributors, and consumers alike. Conversely, a lack of global coordination can lead to inconsistent regulations, trade barriers, and compromised health and safety outcomes (ANSI, n.d.).

Regulations, distinct from standards, are mandatory requirements imposed by governments to achieve policy objectives such as safer products and workplaces (Litan, n.d.). Although regulatory goals may align across nations - and standards greatly enhance this alignment - their implementation often varies due to differing legal, cultural, and administrative contexts (ENHESA, n.d.). Regulatory frameworks serve several key functions. They establish clear, enforceable rules that promote fair competition and protect consumers by ensuring that products meet baseline quality and safety standards. Additionally, they safeguard public health through guidelines that address safety and environmental risks (Abogado, n.d.).

Current standards predominantly focus on respirators for adults and their use in occupational settings. Certain ISO RPD standards extend to the general public (ISO, 2022). Wang *et al.* (2022) provide a summary of the performance requirements for some commonly used international standards for RPD. At the time of writing, there exists only one standard specifically for child respirators: China's GB/T 38880-2020 "Technical Specifications of Children's Masks" (Standardization Administration of China, 2020), which is applicable for children aged 6 to 14. Products conforming to this standard filter particulates in the air, including microbes, pollen, airborne droplets, etc. There are no global (e.g., ISO, ASTM) consensus standards for pediatric respirators.

Although there is an increasing volume of published work relevant to the design of child respirators (Seo *et al.*, 2017; Sucipta *et al.*, 2023; Zhang *et al.*, 2023; NASEM 2023; Goto *et al.*, 2021; Realmuto *et al.*, 2023), this knowledge has not been translated into practice by manufacturers because there is no country or regional regulatory framework available for child applications of RPDs. However, some countries such as China and South Korea, do provide regulatory approvals for respirators designed for children (NASEM, 2023).

Few studies have specifically measured the performance of respirators claiming to fit children. Seo *et al.* (2023) and Gudgin Dickson *et al.* (2025) recently studied pressure drop and filtration efficiency in children's respirators and various non-respirator masks, such as surgical and cotton or cotton-blend cloth masks. All of the respirators in Gudgin Dickson *et al.*'s study met N95 pressure drop requirements but two (out of eight) did not meet the penetration requirements. Additionally, two studies assessed wearability parameters of selected N95/FFP2 respirators for children, including self-reported comfort, measured fit, and gas exchange during rest and light exercise (Goh *et al.*, 2019; Smart *et al.*, 2020; Sleeuwenhoek *et al.*, 2025). Sleeuwenhoek *et al.* (2025) also assessed the fit of respirators on sixty children (30 in Nepal and 30 in Indonesia) using six different earloop respirators (3 in each country) in two combinations (with and without an additional adjustable earloop clip). The fit factor for each respirator was determined using a modified fit test protocol (Appendix II) for filtering facepiece respirators using a TSI PortaCount™ Respirator Fit Tester Model 8048. Most fit factors were less than 10, i.e. less than 90% reduction in exposure. Using an additional earloop clip was associated with increases in fit factor of 42% and 50% for Indonesian and Nepalese respirators, respectively, compared to not wearing an earloop clip.

The physiological effects of wearing respiratory protection at higher activity levels typical of active children have not been systematically examined. However, Smart *et al.* (2020) recorded discomfort due to heat buildup within the respirator during running activities. Sleeuwenhoek *et al.* (2025) found that children who underwent a limited exercise fit test rated the respirators positively across comfort, heat, breathability, perceived fit, embarrassment, and appearance.

The style of a respirator can also influence uptake and use in children. Nila *et al.* (2025) conducted focus group discussions with children in Indonesia and Nepal and asked them to rank respirators in order of their preferred styles and features. Children preferred respirators with earloops rather than headstraps. Younger children tended to prefer coloured and patterned materials whereas older children tended to prefer plain masks (white or black). This suggests that manufacturers could offer a variety of designs to improve uptake in different age groups.

Anthropometric studies offer valuable facial measurement data that could inform the design of pediatric respirators. Using anthropometric data obtained using digitalized 3D face analysis, Kim *et al.* (2016) classified Korean children's facial dimensions to define three appropriate facepiece sizes for protection against yellow dust and fine particulates using anthropometric data obtained using digitalized 3D face analysis. Lin et.al. (2017) developed and evaluated respirator fit test panels for small-to-medium facial features in young adults (age 21-30) and found that fit improved with larger facial dimensions. Sleeuwenhoek et.al. (2025) also measured facial dimensions: face width (Bizygomatic breadth) and face length (Menton-Sellion length) of sixty children in Nepal and Indonesia. They found that, for each mm increase in face length, there was a 2.9% increase in log fit factor, for the Indonesian children.

DEVELOPING GLOBAL STANDARD(S)

The need for a comprehensive approach to pediatric RPDs is increasingly evident. Establishing a standardized global framework that focuses on performance standards, fit assessments, and equitable access is vital. This paper aims to provide general considerations and a framework that a future standards development committee should address.

Aligning international consensus standards with existing conformity systems, such as those of National Institute for Occupational Safety and Health (NIOSH) in the United States, the Conformité Européenne (CE) certification and marking in Europe, and Canadian Standards Association (CSA) in Canada, can streamline the approval, manufacturing, and distribution processes, reducing barriers to adoption. Regional conformity assessment systems, like NIOSH's, could require regional regulatory changes to allow the use of existing frameworks. International efforts like the ISO 16900, 16976 and 17420 series on RPDs provide a framework for this alignment by offering performance-based criteria that can be adapted regionally without compromising safety (ISO, 2021). Each ISO standard number includes a prefix ("ISO"), a series identifier, an optional part number, and a publication year — all of which communicate its scope and industry focus.

If one or more new standards for children's respirators were developed, it would not necessarily render existing products obsolete. Many of the child-sized respirators currently on the market, such as those labeled KN95, FFP2, or KF94, have already been tested against established performance benchmarks for filtration efficiency and, in some cases, breathability. However, while these products may meet technical criteria, the broader regulatory framework needed to ensure appropriate design, labeling, fit, and use for children is often missing. To manage the transition, regulatory authorities could adopt a phased approach: recognizing existing products that meet core technical requirements, while simultaneously setting timelines and guidance for full conformance with the new standard. This would avoid unnecessary waste and supply disruptions, especially given the high volume of products produced by a wide array of manufacturers. The regulatory authority or agency responsible for the new standard could issue a statement acknowledging that certain previously certified respirators remain acceptable for use, provided they meet specified interim criteria. This approach would support continuity in protection while gradually shifting the market toward more rigorously defined and comprehensive child-specific respirator standards.

A comprehensive standardization effort for pediatric RPDs should begin with the development of globally recognized performance requirements, established through an international consensus process involving multidisciplinary experts in respiratory protection, pediatric health, materials science, and human factors engineering. Once developed, these standards guide the design and engineering phase, where manufacturers translate the performance requirements into manufacturing product specifications. This includes the selection of materials, structural components, and features to ensure compliance with the defined pediatric-specific needs. Prototypes should undergo rigorous laboratory testing to verify conformance with performance requirements.

Following successful testing, the certification process—often involving third-party conformity assessment bodies—is used to validate that products consistently meet the standard. Certification should include initial type testing, factory audits, and ongoing quality control monitoring to maintain product integrity throughout the production lifecycle (NIST, 2023). Manufacturers must establish robust quality management systems to ensure repeatability and consistency in mass production, including documentation of production procedures, raw material sourcing, and inspection protocols.

Once in production, regular post-market surveillance, including random batch testing and user feedback collection, is necessary to detect performance degradation or emerging risks. The regulatory framework should also require periodic updates to the standards and certification criteria to incorporate technological advances, updated research data, and improved materials or manufacturing techniques. This full lifecycle approach—from standards development through design, testing, certification, manufacturing, and post-market oversight—ensures that pediatric RPDs remain safe, effective, and responsive to changing needs.

Moreover, it is essential to consider socio-economic factors that impact access to high-quality protective devices. This is particularly important in low to middle income countries where children's exposure to air pollution may be significantly higher than air quality guidance (UNICEF, n.d.[a]). Implementing subsidies or financial assistance programs can ensure that all communities, regardless of economic status, have access to effective pediatric respiratory protection. Collaborative efforts between governments, non-profit organizations, and private sectors could further enhance research and development, addressing specific needs such as fitting adjustments for various age groups and conditions.

A well-rounded and universally accepted framework for pediatric RPDs will not only standardize quality and safety measures but also promote inclusivity and innovation in this critical field.

DESIGN AND PERFORMANCE CRITERIA

Pediatric RPDs require sophisticated engineering to achieve an optimal blend of filtration efficiency, breathability, fit, and comfort. Ensuring effective respiratory protection for children necessitates outlining crucial performance factors. The balance between high filtration efficiency and breathability is essential, as highlighted by ISO (2021), indicating that respirators must not only filter particulates effectively but also allow for easy breathing.

Pediatric RPDs should at least meet these measurable performance requirements: filter efficiency, breathability, and fit. A satisfactory balance of breathability, filtration, and fit is specified by the many global respirator performance standards which are currently referenced in the certification and approval of respirators for adult workers - including N95, FFP2, KN95, and others (3M, 2021). Striking the right balance between these factors is essential for ensuring both safety and wearability. Public health respirator standards, including for pediatric respirators, should be as similar as possible to those existing standards, in the interest of scalability, availability, and elasticity of supply during public health crises.

Other design factors that should be addressed include comfort and acceptability; shelf-life; marking, instructions for use and storage; and reusability, stability, and durability. Respirators with good fitting characteristics are paramount to the effectiveness of respiratory protection. Developing a sizing grid based on studies, such as the Korean study identifying three respirator sizes (Kim *et al.*, 2016), could establish a baseline for pediatric respirator sizing. Additionally, sizing may need to be done in different geographical regions to address differences in facial anthropometry, to ensure a respirator fits a person's unique facial dimensions well enough so that the respirator is offering the optimal level of protection for which it was designed (Hasni *et al.*, 2023; Hobbs-Murphy *et al.*, 2025; O'Kelly *et al.*, 2021; Yu *et al.*, 2014).

When designing pediatric respirators, physiological differences need to be considered. Age-appropriate designs should accommodate children two years and older (CDC, 2025). In addition to the above mentioned measurable performance requirements, effective pediatric respirators should prioritize comfort, usability, and inclusivity. Materials used should minimize discomfort while maintaining protective integrity, as noted by Holm (2022). Furthermore, inclusive design should ensure that devices meet the needs of children with developmental challenges and hearing impairments (ISO, 2021).

Safety considerations are critical to guarantee effective and safe respiratory protection for children. Pressure drop analysis indicates no significant physiological effects on heart rate, oxygen saturation, or respiratory rate while wearing surgical masks or FFP2 respirators, according to Happernegg *et al.* (2023). Most studies report no adverse effects from product use; however, further evaluation of CO_2 retention in child-sized respirators is necessary to ensure safety, as highlighted by Lubrano *et al.* (2021), Weigelt *et al.* (2024), Mull *et al.* (2021) and Goh *et al.* (2019).

Several key areas must be addressed in a global standard, to optimize the real-world effectiveness of pediatric RPDs:

Particulate Filtration Efficiency

Filtration efficiency measures how effectively a respirator can filter out particles from the air. High-efficiency respirators, such as N95 filtering facepiece respirators (FFRs), are designed to capture at least 95% of airborne particles, including harmful pathogens, dust, and particulate pollutants (Rengasamy *et al.*, 2017; NIOSH, 2021). This effectiveness is achieved by employing multiple layers of advanced materials such as melt-blown polypropylene, electrostatic filters, or nanofiber technology. However, higher filtration efficiency often comes with increased resistance to airflow, which can make breathing more difficult. For example, respirators that offer protection against oil-based aerosols or smaller particles may have denser filter media, thereby reducing breathability. To optimize protection from both particulate pollution and pathogens, children's RPDs should meet the same filtration efficiency performance standards as adult respirators. For pediatric respirators, flow rate and aerosol loading are essential parameters in particulate filtration efficiency testing because they ensure the device can provide consistent protection under realistic and worst-case use scenarios for children. Flow rate should be adjusted to reflect pediatric breathing patterns, which vary by age and activity level, but still need to account for elevated exertion during play or physical activity (Gudgin Dickson *et al.*, 2025). Testing at appropriately scaled higher flow rates helps ensure the respirator maintains filtration performance even when a child's respiratory rate increases. Similarly, aerosol loading evaluates how filter performance changes as particulates accumulate during extended wear. Some filter media may initially perform well but degrade as they load, particularly in designs that rely on electrostatic charge. Understanding how pediatric respirators behave under both high-flow and loaded conditions ensures that they maintain protective efficiency throughout their intended duration of use and supports the development of performance standards that are appropriately scaled for children's unique physiological and behavioral characteristics.

Breathability Optimization

Breathability refers to the ease with which air passes through the respirator and reaches the wearer. It is dictated by factors such as the structure of the respirator, the materials used, and the overall design, including fit. Lightweight and low-resistance non-respirator products, such as surgical masks, may provide better breathability but may compromise on filtration efficiency. Manufacturers assess breathability using measurements like pressure drop, which quantifies the resistance of airflow across a respirator's material. Lower pressure drop values correspond to easier breathing, making the respirators more suitable for prolonged use, particularly in physically demanding environments or for individuals with respiratory conditions.

The relationship between breathability and filtration efficiency is often inversely proportional. As filtration efficiency increases, breathability tends to decrease due to the denser material makeup required for high-level filtration. Balancing filtration efficiency with breathability is crucial for comfort and extended wear. Recent advances in filtration media enhance protection while simultaneously offering low airflow resistance. Innovations in materials science also promise to create lightweight yet durable facepieces, which could be pivotal in promoting wider acceptance and usage. Further research could explore alternative manufacturing techniques incorporating porous membranes and microstructure adaptations to improve breathability without compromising filtration efficacy.

Breathability-focused modifications, such as specialized exhalation valves or adjustable airflow features, might be designed specifically for respirator applications, although these present challenges in child respirators due to the reduced area of filter medium (Goh *et al.*, 2019). Additionally, ergonomic designs, like horizontal fold FFRs, that consider facial structures and movement patterns could further optimize the breathability, comfort and usability of pediatric respirators, ensuring effective use in varied environments and conditions.

Gudgin Dickson *et al.* (2025) suggest that, due to the physiological and anthropometric differences between children and adults, further work to help define requirements and standards appropriate for specifically testing children's respiratory protection is warranted. For example, they evaluated test flow rates representative of typical children's breathing patterns. Child-specific flow rates should be considered in performance testing of filtration efficiency and pressure drop.

Fit Capability

Ensuring proper respirator fit is vital for protecting children. Respirator fit is a critical consideration because effective contact between the respirator and the wearer's skin, around the full perimeter of the respirator, including the bridge of the nose, directs air through the filter rather than allowing it to flow around the respirator and directly into the child's airways. The effectiveness of a respirator seal can be compromised by gaps between the face and the respirator, which underscores the necessity for fit data that better represent children's facial features (Hasni et.al., 2023; Xu *et al.*, 2021).

Pediatric respirator fit needs to be addressed in two ways. First, the capability of the respirator design needs to be addressed by the performance standard - this is explored in this section. Second, the fit of a particular respirator that is selected for use by a particular child needs to be confirmed before the child wears the respirator into a hazardous environment, since no one respirator model effectively fits every single face. This is explored in the Regulatory Framework section of this White Paper. It is important to note that, usually, fit and comfort are opposing factors. Often, masks and respirators that fit poorly are perceived to be the most comfortable, because they allow more air to enter freely around the sides of the respirator. A proper balance must be established between fit and comfort.

Measurements of respirator fit are called fit factors. A lower fit factor on a respirator indicates a weaker or incomplete seal between the facepiece and the wearer's face. This compromised seal allows for an increased level of leakage, diminishing the respirator's overall effectiveness in filtering harmful contaminants. In practical terms, this means that the child wearing the respirator may inhale a greater proportion of airborne particles, which the device is intended to block.

Several factors can contribute to a lower fit factor, including an ill-fitting design that does not adequately contour to the face, as well as anatomical variability and compliance considerations (Sleeuwenhoek *et al.*, 2025; Brosseau, 2010), improper donning of the respirator, or wear-and-tear over time. A low fit factor is a clear signal that adjustments are necessary, whether through selecting a new or better-fitting respirator model, using accessories to improve fit (such as earloop clips), or educating the child and caregiver on proper use.

A test to measure a fit factor is called a fit test. Ideally, fit test protocols simulate real-world use conditions, such as speaking or head movements. Conducting a series of fit tests on a variety of wearers is called a fit study. Fit studies must be conducted using human subjects - no researcher has to date developed a headform, static or dynamic, that yields fit measurements that correlate with fit measurements on human faces. If the wearers in a study are selected methodically, to be representative of a broader population, that study is called a fit panel. Typically, for adult respirators, fit panels are assembled based on face sizes typical for that adult population, with a certain number of participants from each face size, distributed according to the whole population face size distribution. For children, a similar practice could be effective, and should include children who must use various head-worn items such as glasses, hijab, turbans and orthodontic equipment. However, given the wider range of face sizes due to the fact that children grow and develop at different rates, it is possible that a child panel would be assembled based on ages rather than face sizes. This method of assembling a panel has been used when a face size grid was not available for a child population (Sleeuwenhoek *et al.* 2025).

Developing anthropometric face measurement databases for children is of paramount importance, as they can be used to develop facial dimension grids representative of specific child populations, which are essential for designing protective equipment, such as respirators, that fit securely and function effectively (Zhuang *et al.*, 2007). Nemeth *et al.* (2025), found facial shape and size in children vary significantly with age from ages 2 to 18, and offered guidance on how qualitative analysis can be used for the design of pediatric RPDs. In designing children's respirators that are both effective and equitable, global standards should incorporate regional flexibility to address the demographic variability (e.g., facial anthropometry, age, sex, and facial features) specific to different populations. Pediatric respirators designed for one demographic may not fit or function optimally for another; for instance, studies have shown that standard respirators often fail to provide an adequate seal for individuals with smaller or flatter facial profiles, which are more common in some Asian populations (Zhuang *et al.*, 2010).

Anthropometric face measurements could also be used to inform respirator labeling to guide consumer size selection. Non-invasive optical scanning technology, like using an app on a cellphone, presents an opportunity for manufacturers to improve pediatric respirator designs before they reach the market.

A comprehensive standard would need to specify fit performance criteria. The standard should allow maximum innovation in product design by dictating performance requirements, not specific design elements. A key consideration in respirator design is the difference in performance between earloops and head straps. While elastic head straps have shown to provide improved fit and stability (Bergman *et al.*, 2012), most children's respirators, especially in low-resource settings, rely on earloops due to ease of use, manufacturing constraints, and the preference of users who prefer comfort but lack awareness of the differences in performance between earloops and headbands. Novel head suspension systems, such as adjustable harnesses or hybrid configurations that combine earloops with an optional overhead strap, may be alternatives to consider for improving fit. Including fit performance criteria in the product standard would compel manufacturers to develop well-fitting child respirators via a wide range of solutions.

Manufacturers should consider design elements that can help ensure good fit across the full spectrum of face sizes in pediatric populations. Standards and user instructions could, and arguably should, include information on improving respirator fit through additional methods, particularly for children. For example, Sleeuwenhoek *et al.* (2025) demonstrated that the use of an earloop clip, connecting the earloops at the back of the head, significantly improved fit for particular child respirators by reducing gaps and enhancing seal integrity. The research in Sleeuwenhoek *et al.* (2025) was part of the FACE-UP project which subsequently incorporated such findings into its informational products (an animated video for children and a booklet for parents/carers), recommending practical accessories like earloop clips and, in their absence, alternatives such as hair clips to tighten the facepiece effectively. Fit improvement techniques such as these could vary in effectiveness by respirator and should be evaluated, perhaps by manufacturers (FACE-UP, 2025).

One could look to occupational FFRs as a model to establish the fit capability requirements for child respirators. In workplaces, employers must measure the concentration of the hazard and then ensure that a respirator provides enough protection to reduce the concentration that is inhaled by a worker to an acceptable level that will not damage their health. For workers, fit factors of 100 are typically required during a fit test, in order for an FFR to be considered sufficiently well-fitting for that workplace use. A fit factor of 100 typically means the respirator is capable of providing a 100-fold reduction in the amount of particles inhaled by the wearer - or 99% reduction (1/100). However, because fit tests are very controlled measurements, regulators apply a research-supported safety factor of 10 to estimate the actual protection provided when the worker wears that respirator during work. Therefore, a fit factor result of 100 is interpreted to mean that when a fit-tested worker wears that FFR in their workplace, they are assumed to receive overall protection of at least a 90% reduction (1/10) in contaminants. Therefore, if workplace concentrations do not exceed 10 times the acceptable concentration, the worker is assumed to be effectively protected by the FFR.

Typically, fit capability performance criteria are expressed in terms of a percent pass rate at a specific fit factor. For example - for an adult workplace respirator design, a reasonable acceptance criterion could be "a 65% pass rate at a fit factor of 100." If a design has a lower pass rate than that, it might not be well accepted by customers, since many wearers would fail fit tests. However - for pediatric respirators, since most children cannot be expected to be fit tested, it is reasonable for the pass criterion to include a higher pass rate. Regulators would want to be sure that a design has a high probability of providing a certain level of protection, when used correctly.

Significant questions that need to be addressed by standard developers and regulators are: What is an acceptable fit factor criterion for child respirators? What reduction in contaminant concentration is acceptable? As mentioned earlier, fit and comfort are often inversely related - as fit improves, there is a decrease in comfort; as fit deteriorates, comfort can seem to increase, due to air flowing freely around the edges of the respirator. A balance must be struck, where child wearers are adequately protected but not over-protected at the possible expense of comfort and uptake (or effective use). Section 4, below, explores features that impact comfort and acceptability.

It is perhaps reasonable for the acceptance criterion to specify a lower fit factor than 100. Factors that must be considered are: typical particulate matter concentrations and levels that are considered to be acceptable for a given population or individual. The ratio of concentration to acceptable level is the reduction that is needed. For example, the World Health Organization (WHO) recommends that 24-hour average $PM_{2.5}$ levels should not exceed 15 μg/m^3 more than 3-4 days per year. $PM_{2.5}$ concentrations routinely reach 100 μg/m^3 in parts of the United States affected by wildfire smoke (Childs *et al.*, 2022). To reduce 100 μg/m^3 to below 15 μg/m^3, a reduction factor of 6.7 is needed. With a safety factor of 10 applied, the fit test fit factor should be at least a 67. Therefore, a possible acceptance criterion to consider, based on this logic, could be at least an 80% pass rate at a fit factor of 70. It is also possible to set multiple performance criteria - such as, the design must achieve at least an 80% pass rate at a fit factor of 70, and at least a 95% pass rate at a fit factor of 5. A fit factor of 5 represents an 80% reduction in exposure (1/5). A historical precedent to consider is the FDA-approved public health respirators, for which the DeNovo (new product) application specified a fit performance of a 100% pass rate at a fit factor of 2 (a 50% exposure reduction, 1/2).

Finally, a fit study protocol needs to be designed. Since children are not likely to have access to individual fit testing, one way to meaningfully assess a respirator design's ability to fit in real-world use is to conduct an unassisted study (3M Personal Communication) (Appendix II).

Manufacturers that have developed and commercialized child respirators, and that have internal acceptance criteria and testing procedures, should be consulted in the development of at least the fit performance portion of the pediatric respirator standard.

Ideally, individual fit tests would be conducted on children needing respiratory protection. The availability of such fit testing services might result in changes being made to the fit performance criterion specified by a pediatric respirator performance standard.

Comfort and Acceptability

Comfort in pediatric respirator design extends beyond functional aspects and breathability; it also encompasses careful consideration of design elements that directly impact user experience. Ensuring that respirators lack sharp edges or coarse materials is imperative to prevent irritation or discomfort during prolonged use. Rough textures can lead to skin chafing, particularly on sensitive areas of a child's face, such as the nose bridge and cheeks. Similarly, the use of staples to attach straps, while seemingly negligible, may pose risks if exposed or ingested, causing discomfort or potentially injuring the user.

Manufacturers should instead opt for seamless, padded, or ergonomically contoured designs that evenly distribute pressure and minimize localized strain (Smart *et al.*, 2020). By integrating these thoughtful design elements alongside functional performance, pediatric respirators can achieve a balance of safety, usability, and comfort, which is critical for encouraging consistent use among children.

To enhance comfort for extended pediatric use, it is essential to consider several factors. Firstly, using hypoallergenic materials can significantly reduce skin irritation, which is particularly important for individuals with sensitive skin or allergies (Smith, 2022). This choice of material ensures that the respirator remains comfortable over prolonged periods, minimizing discomfort and potential allergic reactions. Secondly, incorporating moisture-wicking and ventilated layers aids in temperature control (CDC, 2025a). These features help manage perspiration and heat build-up, making the respirator more suitable for long-duration wear, especially in warmer environments. Facial seal pressure is another important attribute for comfort that should be considered.

For children, more than adults, how they appear while wearing a respirator or facemask will influence their willingness to use the intervention (Le et.al., 2023). The shape, color, and pattern of the facepiece are all, likely, influential (Smart *et al.*, 2020; Sleeuwenhoek *et al.*, 2025; Nila *et al.*, 2025). A global standard should be sufficiently flexible to allow for varied designs, potentially including non-typical respirator designs such as gaiter-style coverings (also known as snoods or buffs). With conventional styles, there is evidence that horizontal-folded facepieces fit better on children than vertical-folded facepieces, which often are too large around the nose and chin areas (Sleeuwenhoek *et al.*, 2025). However, vertical-fold facepieces are more commonly available (and are worn more frequently by adults, with children modelling adult behavior; Kendal *et al.*, 2018) in some parts of the world.

Designs should also prioritize usability and intuitiveness, ensuring that children can easily adjust and wear the respirators without complex instructions or external assistance. Features such as simple strap mechanisms, clear markings for proper orientation, visual cues for fit adjustments like forming the nose clip, and ability to accommodate a variety of hairstyles, eyewear, and headwear accessories can make respirators more user-friendly for children. It is important for a design standard to encourage designs that are most likely to fit, and be appealing to, a wide range of children (Nila *et al.*, 2025).

Pediatric respirators should also be acceptable to parents and caregivers, particularly of younger children, as their willingness to purchase such devices directly influences compliance and effectiveness. Acceptability hinges not only on functional attributes but also on cost, availability, and design aspects (ease of adjustment, visual appeal, perceived comfort, and packaging design). Providing clear instructions and educational materials tailored for caregivers ensures proper usage and maintenance, fostering a positive experience and promoting consistent use among young users (CDC, 2025).

By designing children's respirators that fit well and distribute pressure evenly, users can avoid areas of discomfort that may develop during continued use. These combined strategies create a more practical and user-friendly respirator experience, promoting health and safety without sacrificing comfort.

Marking, Instructions for Use, Storage and Shelf-life

Improving compliance and effectiveness through clear and accessible usage guidance is crucial. To aid children and caregivers, package marking should incorporate pictorial representations in conjunction with culturally appropriate instructions for use. Manufacturer instructions should provide guidance for reuse and care in the instructions. Consideration should be given to the role that carers must play in helping the child wearer put on and check the fit of the respirator. It is essential that the manufacturer instructions be specifically written to be understandable and executable by carers and children, including how to put on the respirator, limitations, and how to conduct seal checks. Checking and troubleshooting the seal of a respirator is vital to helping optimize the protection that the respirator delivers, and it is important for manufacturers to recognize and address the fact that seal check procedures for adults likely need to be modified or explained differently to be understood and done effectively by children and their carers.

It is best practice for regulatory authorities to evaluate the effectiveness of manufacturer user instructions during the approval process, to help ensure that the instructions document is complete and understandable by the end user. Standardizing fit adjustment accessories and instructions across different pediatric respirator models, if practicable, can ensure consistency and facilitate ease of use for all users. An example of this would be the inclusion of earloop clips. Furthermore, public health education programs should provide comprehensive instructional materials that detail the procedures for selecting, maintaining, and disposing of children's respirators. These measures can enhance understanding and proper usage, ultimately contributing to better health outcomes and overall safety.

Improper storage such as exposure to extreme temperatures, high moisture, or UV light, can lead to degradation of filter media and loss of electrostatic charge, compromising filtration efficiency, as well as degradation of elastic/rubber straps. NIOSH has documented several cases where expired or improperly stored respirators failed to provide adequate protection, highlighting the importance of adhering to manufacturer-recommended storage conditions and shelf lives (NIOSH, 2025). These reports have shown that expired or improperly stored N95 respirators experienced increased fit failures and decreased performance, emphasizing the need for routine inventory checks and adherence to stock rotation practices. Ensuring proper storage in a clean, dry environment and within the manufacturer's specified temperature and humidity range is essential to maintaining respirator integrity and user safety.

Respirator shelf-life and proper storage conditions are critical to ensuring the effectiveness and safety of all RPDs, including those for children. Shelf-life varies by manufacturer and model but is generally affected by environmental factors such as temperature, humidity, light exposure, and packaging integrity (NIOSH, 2020). Typical shelf-life for currently available RPDs range from 2-5 years.

Shelf-life is an important consideration in respirator performance and inventory management, although its treatment varies across regulatory frameworks. For example, in the United States, NIOSH does not specify shelf-life and storage method as part of its certification process under its regulation, 42 CFR Part 84, apart from identifying a shelf-life requirement for escape respirators used in mining and chemical, biological, radiological, and nuclear (CBRN) applications (NIOSH, n.d.). It is the responsibility of manufacturers to determine and label shelf-life based on internal testing (NIOSH, n.d). EN 149 requires labeling indicating that the shelf-life should be provided in the marking, but it does not give any requirement for shelf-life length (BSI, 2001).

Reusability, Stability, and Durability

Pediatric respirator designs need to be robust enough to maintain their functionality through the period they are in use. Some respirators are designed to be used for a short period (like FFRs), and some, like elastomeric respirators, are designed to be more durable and robust, with facepieces made of plastic, rubber, or silicone (which can be cleaned/disinfected) and replaceable filters (which cannot be cleaned). FFRs are not intended to be cleaned or disinfected; however, they may be reused. Both FFRs and elastomeric respirators are intended to eventually be discarded when they no longer pass inspection according to procedures which should be recommended by the manufacturer. Features to be inspected may include rips or tears of the facepiece, stretching or breaking of the head straps or earloops and, for FFRs, ensuring the noseclip is intact and bendable and that the inside of the facepiece is not dirty or otherwise contaminated.

Particle filters in most particulate respirators become more efficient as they collect particles during use. Eventually, as the filter accumulates more particulate matter, however, the user might notice that it is harder to breathe through and discard and replace the filter or FFR.

Ideally, children's respirator designs and/or packaging would incorporate clear indicators of wear-and-tear to signal when they need replacing. By doing so, users and caregivers could ensure optimal protection and timely replacements. Manufacturing strategies should also prioritize affordability, to make pediatric respirators accessible to families across different socioeconomic backgrounds. This approach will help more children, regardless of their financial situation, have access to reliable respiratory protection.

MANUFACTURING AND DISTRIBUTION

Efforts to improve the accessibility and affordability of children’s respirators require strategic coordination among multiple stakeholders, including manufacturers, public health authorities, and governments.

The creation of selection guidance by local, regional, or global public health authorities, which references scientifically sound children’s respirator performance standards, such as those that are currently queued for development by ISO and ASTM, will help to create favorable market conditions for high-performing new pediatric respirator products, designed and manufactured using sound quality control practices by reputable manufacturers.

The global children’s facemask market, which includes respirators, is experiencing robust growth. It is projected to reach $2.5 billion in 2025, with a compound annual growth rate of 8% extending through 2033 (Archive Market Research, 2025). This growth is driven by heightened awareness of respiratory health and air pollution, an increase in allergies and infectious diseases among children, and stringent public health regulations. Technological innovations, such as enhanced filtration capabilities and the use of eco-friendly materials, are further fueling this market expansion. While non-certified facemasks and FFRs currently dominate due to convenience and affordability, the elastomeric style is gaining popularity, largely due to environmental concerns and long-term cost savings(Archive Market Research, 2025).

The 2–6-year-old age group represents the highest demand segment, with market concentration primarily in North America and the Asia-Pacific region (Archive Market Research, 2025). These areas benefit from high population density, rising disposable incomes, and elevated health awareness (Archive Market Research, 2025). However, demand is expected to grow across all global regions, particularly in developing economies with expanding middle-class populations. Despite the positive market outlook, challenges remain. These include fluctuations in raw material costs, seasonal demand variations, and stringent regulatory compliance requirements in certain jurisdictions (Archive Market Research, 2025).

Cost instability, driven by unpredictable demand spikes, is a concern in the production and scalability of pediatric respirators. Emergency preparedness plans must include scalable production mechanisms to respond rapidly during health crises. There is a potential for international child and health-focused humanitarian agencies to support market stability through agreements with RPD manufacturers, to ensure availability of sufficient unexpired RPDs during air pollution and public health crises. Collaboration between governments, manufacturers, and public health agencies can help align standards and improve access to high-quality pediatric respirators (UNICEF, 2021a). These partnerships can also facilitate knowledge sharing and promote innovation. Equitable distribution is essential, especially in low- and middle-income countries, where children face disproportionate barriers to accessing respiratory protection (McDonald *et al.* 2020). Supply chain disruptions can significantly limit availability, making it crucial to build resilient logistics networks and harmonized global standards, so that products from one market can easily be applied to a different market. Additional strategies to improve accessibility include offering pediatric respirators through online marketplaces, distributing them at local community events, and implementing subsidy programs for underserved populations.

Governments face complex decisions when allocating limited public health resources, particularly when balancing the need for children's respiratory protection against other pressing priorities such as vaccination programs, mental health services, nutrition, and chronic disease prevention (McDonald *et al.* 2020). The manufacturing and distribution of pediatric respirators require a coordinated, multisectoral approach involving manufacturers, public health agencies, policymakers, and communities. Stockpiling is an essential component of disaster preparedness planning. However, without a standard defining the performance requirements for pediatric respirators and regulations requiring that products meet those standards, stockpiling organizations lack the guidance needed to create effective specifications in bids.

LOCAL REGULATORY FRAMEWORK

A robust local regulatory framework is essential for ensuring that children’s respirators meet the necessary safety and performance requirements, using existing, well-established respirator standards, with the ability to incorporate child-specific standards as they are published. Such a framework should be implemented locally, at the country or region level, and should include these components:

- Pediatric respirator performance requirements
- Approval or registration requirements
- Selection and use guidance
- Consideration for equitable distribution, access, and education

Two framework options that incorporate these components are given below.

Pediatric Respirator Performance Requirements and Approval or Registration Requirements

Option 1 - Approval Program

Lawmakers in each country would designate a regulatory authority or agency responsible for overseeing approvals of pediatric respirators to acceptable performance standards (see Design and Performance Criteria, above). This agency, ideally one with existing expertise in PPE, aerosol science, and inhalation protection, would be tasked with setting and enforcing performance criteria. For example, for occupational respirators in the United States, approval is currently overseen by NIOSH's National Personal Protective Technology Laboratory (NIOSH, n.d.). The regulatory framework considered for a children's respirator standard should, at a minimum, require that an accredited testing lab (one that meets international quality rules under ISO/IEC 17025), which is independent of the manufacturer, evaluates the respirators against a standard. Independent validation ensures that products meet standardized performance thresholds, which is especially vital for protecting children. Third-party testing - by either the approval agency or independent laboratories - also fosters consumer and institutional trust, which is essential for public acceptance and widespread adoption. Incorporating certified testing laboratories into the regulatory approval process helps mitigate risks associated with substandard or counterfeit products and aligns with best practices observed in adult respiratory protection standards.

The regulatory authority would either develop its own performance regulation or, preferably, adopt or reference a high-quality international consensus standard (like an ISO or ASTM standard) tailored to pediatric respiratory protection. In some jurisdictions, suitable standards already exist. For instance, China's KN95 standard allows children to be used in Total Inward Leakage (TIL) testing if the manufacturer designates children as the target user group (Standardization Administration of China, 2019). Similarly, Korea's KF94 consumer respirator standard provides performance benchmarks relevant for children's respirator products (Korea Ministry of Food and Drug Safety, 2020). A global standard could be adopted by regions that have established regulatory frameworks and actively support participation in the global marketplace, promoting consistency, safety, and trade efficiency across borders.

Regional adaptation within harmonized global standards is key - for example, defining required facial panels representative of local populations. The World Health Organization's (WHO) guidelines allow for context-specific implementation while maintaining core safety principles (WHO, 2021). Incorporating modular design features, such as adjustable straps or interchangeable filter media, and promoting local production with certified materials can also support regional adaptability while maintaining compliance with overarching certification requirements. This approach is exemplified by India's BIS-certified FFP2 standards, which align with European norms but include provisions for local high-dust environmental conditions by including a clogging test using coal dust or dolomite (Bureau of Indian Standards, 2002).

To ensure compliance, the agency should define conformity assessment procedures. This includes requiring manufacturers to submit test data from accredited laboratories and possibly verifying the qualifications of these labs. Where feasible, the agency may also perform independent testing. The burden of proof requirements should be transparent and consistent.

A comprehensive approval program should extend beyond initial product testing to include:

- Verification of manufacturing site qualifications (to reduce counterfeit risks)

- Product marking and labeling requirements
- Review of user instructions
- Assessment of product-specific quality plans
- Manufacturing site audits
- Post-market surveillance and performance verification

These elements ensure sustained product quality and performance over time.

Option 2 - Registration Program

Another feasible model that countries could consider is a product registration approach, where a country would recognize the approval or certification of another country, requiring manufacturers selling in their country to provide documentation of the approval or certification they hold from the approving country. This is an especially advisable option for smaller countries with little or no domestic respirator production or smaller market sizes. Creating a unique approval program in such countries could discourage established, reputable manufacturers from selling into those markets altogether; a registration program is a more appropriate regulatory approach.

Selection and Use Guidance

In parallel with performance regulation, guidance for the selection and use of pediatric respirators should be developed by regional public health authorities in alignment with global health (e.g., WHO or UNICEF) respirator selection recommendations, as they become available. These agencies should collaborate with occupational health experts as well as pediatricians and public health experts to provide evidence-based, accessible user guidance, potentially based on international guidelines (there are plans for their development). Ideally, the agency or agencies responsible for issuing such guidance would have a) authority related to environmental airborne contaminants, b) expertise on environmental health principles, and/or c) responsibility for population health - such as the Environmental Protection Agency or Center for Disease Control and Prevention in the United States and similar agencies in other countries.

Selection and use guidance for pediatric respiratory protection should include, at a minimum:

- When - Under which circumstances should caregivers consider having children use respirators - e.g., what environmental conditions or circumstances, identifying precise thresholds when possible
- Who - Which children should use respirators and which should not use respirators
- Which - What is the correct respirator type for the hazards that are present in a given situation
- How - How to correctly put on a respirator, with acknowledgement of model-specific user instructions, how to confirm that a respirator is well fitted and positioned, to optimize the likelihood that the respirator is providing the expected degree of exposure reduction

When to Use Respirators

Families and caregivers need clear, consistent, actionable guidance regarding when children should wear respirators. Air quality events may be caused by natural events such as wildfires or volcanic eruptions, or may be caused by humans, such as vehicle- and industry-generated particulate matter. Weather patterns influence the severity, duration, and geographic range of air quality events. Air quality is measured and air quality indexes (AQI) are calculated and reported in countries around the world. Some programs forecast AQI days into the future. Ratings and unhealthy thresholds are identified by environmental health authorities, and many countries have established systems for issuing Air Quality Alerts, often via weather alert systems, typically disseminated via web applications, television news, and radio. Ratings, threshold, and alert systems often include guidance to the public, such as reducing vehicle traffic, avoiding spending time outdoors, etc. Such guidance should also address whether and when (at what concentration thresholds) respiratory protection should be worn by sensitive populations if they cannot avoid spending time outdoors, for example children traveling to school, doctor appointments, or unavoidable family errands.

Which Children Should Use Respirators

Agencies should provide guidance to families regarding which children should not wear respirators. For example, the UK Health Security Agency (formerly Public Health England) and the US CDC had recommended against the use of respirators and non-respirators in children under two years of age or in individuals with conditions that prevent proper use (CDC, 2025a; PHE, 2020). Some experts have recommended that anyone - children or adults - who do not have the ability to remove the respirator should they want to - such as individuals with physical or mental impairment - should not wear a respirator. Guidance should also emphasize the importance of avoiding exposure, if possible, and only relying on respiratory protection when it is not possible to avoid exposure - e.g., to travel to school, but not to attend sports practices that could be canceled during an air quality crisis.

Which Respirator Type

As part of the reporting and guidance provided by agencies, there should be recognition that certain respirators are effective against certain hazards - and the limitations of, for example, an FFR should be communicated to families. It is important for parents and caregivers to understand that particulate respirators, such as N95s and other FFRs, provide protection against particulate hazards such as $PM_{2.5}$, but not against gases and vapors. A majority of environmental airborne hazards are particulate hazards - $PM_{2.5}$, pollens, mold spores, etc. However, there are gases and vapors that are present in air pollution - carbon monoxide, ozone, nitrogen dioxide, sulfur dioxide, and VOCs - that are not captured at all by the filter material in FFRs but may be reduced if the respirator features activated carbon. Families must fully understand the limitations of the respirators available to them, to make informed decisions about risk; this is an important consideration for education, as addressed in the next section of this White Paper, as well as for the regulatory framework. Agencies reporting air quality should highlight the hazards that are present on a given day.

How to Use Respirators

Finally, the authoritative agency or agencies should issue guidance on how to correctly put on respirators and assess their effectiveness. Guidance should be coordinated, aligned with, and amplified by the education efforts described below. Respirator fit capability is tested with the respirators worn correctly, and so it is important for users to wear respirators according to the manufacturers' recommendations. It is important for respirators to contact the wearer's face around the full perimeter, to help ensure that inhaled air travels through the filter rather than around the respirator. Therefore, caregivers must be advised of the importance of assessing the fit of the respirator on their child's face.

Ideally, every child needing a respirator would undergo a fit test to confirm that their particular respirator can seal well enough to their particular face to provide the expected level of protection. However, fit tests are not typically available to children. Public health agencies should consider developing community-accessible fit test services. Individual fit testing would need to be repeated at some frequency - likely annually - given how quickly children grow. Previous successful public health and safety programs that can serve as examples for this include vaccination programs and child safety seat assessment programs. Suggestions for child respirator fit testing programs have included making them available for free or for nominal fees at fire stations, provided by emergency responders (similar to a child car seat assessment in some countries); at schools, provided by school nurses; and at pharmacy clinics, provided by pharmacy technicians (similar to annual vaccines).

If child respirator fit testing services are not available, children can and should perform self-evaluations of a respirator's seal with guidance from, and close observation by, their caregiver. User guidance should instruct caregivers on how to identify and troubleshoot possible poor fits. Instructional videos can be extremely helpful.

Considerations for Equitable Distribution, Access, and Education

At-risk and disadvantaged populations consistently have less access to effective health interventions (Bright *et al.*, 2017). Public health authorities should consider the cost and availability of effective pediatric respirators in their countries for the populations who need them. The regulatory framework described in this section, once in place, will help ensure that pediatric respirators sold within a given country will be tested to science-based, effective standards. Cost and convenient access could still be challenging. Community stockpiles should be considered - purchase requests to supply the stockpiles should specify reputable standards or national approval programs. During acute air quality events, stockpiles should be distributed to impacted populations. Additionally, free or subsidized distribution via public schools could be an effective means to ensure that families have access to affordable pediatric respirators.

EDUCATION, TRAINING, AND COMMUNICATION

Public education is crucial for improving respirator use compliance. Effective methods for educating children on respirator use should be engaging, age-appropriate, and involve caregivers in their design and dissemination, as well as educators and health professionals.

One of the best practices for teaching children about respirator use is to provide age-appropriate instruction that aligns with their cognitive and emotional development. Educational strategies that incorporate visual aids, storytelling, and simple analogies can effectively convey the importance of pediatric respirators in a way that resonates with young learners. Interactive activities such as role-playing, games, and hands-on demonstrations allow children to practice using respirators in a fun, engaging, and memorable manner. These types of developmentally appropriate teaching practices must be adapted to age, development, individual characteristics, and the family and social and cultural contexts of each child served (National Association for the Education of Young Children, n.d.; National Center on Safe Supportive Learning Environments, 2025). By fostering familiarity and comfort with respirator use early on, children are more likely to adopt these practices during times of heightened health risk, such as during influenza season or in the event of a public health emergency.

Hands-on demonstrations should show the proper use of pediatric respirators with step-by-step guidance, allowing supervised practice to ensure correct fit and comfort. Guidelines provided by NIOSH and OSHA on fit testing and seal checks in occupational settings can be very useful as a template for these demonstrations. (NIOSH, 2018; NIOSH, 2025a; OSHA, b.)

Integrating respiratory protection education in health education and advocacy from pediatricians to help educate caregivers and children to introduce the concept of respiratory protection can also be highly beneficial. By including such education in science and health curricula, schools can link it to broader topics such as air quality and respiratory health. Regular reinforcement from teachers and school nurses can further solidify this knowledge. For example, Christiansen et.al. (1997) conducted an evaluation of a school-based asthma education program for inner city children which showed that child-centered asthma education can be successfully conducted in the school setting.

Parental and caregiver involvement is critical to effective pediatric respirator use education. Educating parents on the proper selection and fitting of children's respirators, as well as conducting training sessions to help caregivers ensure correct usage, is vital. Families should be encouraged to practice putting on and taking off the respirator, following the manufacturer user instructions, including forming the nose clip and conducting a seal check.

Digital and media resources can enhance learning experience. Videos, including animations, offer engaging demonstrations of respirator use, while child-friendly infographics highlight key concepts. For example, the FACE-UP project has created a children's 90-second animation about air pollution and how to fit a respirator, co-designed with children who suggested the characters that they would best learn these public health messages from, thus incorporating their social learning strategies (Kendal *et al.*, 2018; FACE-UP, 2025). The project also co-designed (with parents, teachers and agencies) a detailed booklet for caregivers and educators on protecting children from air pollution (FACE-UP, 2025).

Educational programs should also inform caregivers and children that different types of face coverings and respiratory protection offer different levels of protection. Without this knowledge, people can use face coverings with low protection ability, thereby producing a false sense of security (Mueller *et al.*, 2018; McDonald *et al.*, 2020).

Finally, addressing common concerns about pediatric respirator use is important. Providing reassurance regarding the comfort and effectiveness of pediatric respirators can reduce apprehension. Peer modelling can encourage adoption among children (Kendal *et al.*, 2018), and countering misconceptions with science-backed information from trusted sources such as UNICEF helps establish confidence in pediatric respirator use.

Incorporating comprehensive and interactive educational approaches within public and school health programs, involving caregivers, and leveraging digital resources might significantly improve respirator use compliance among children. An example of this approach used in another setting was a systematic review of pediatric asthma management which showed that digital interventions, like apps, text reminders, and websites, when combined with educational content and behavioral strategies, significantly improve children's adherence to inhaler use and overall asthma control. These interventions often involve both caregivers and clinical support (Ramsey et.al., 2020).

ETHICAL AND CULTURAL CONSIDERATIONS

Pediatric respirators are intended for general health protection rather than occupational use. Guidelines should clearly state their purpose to prevent misinterpretation and misuse in workplace settings. International standards by organizations such as ISO should reinforce this distinction by emphasizing appropriate application scenarios for RPDs (ISO, 2021).

Parents and caregivers should be provided with clear, transparent information regarding the benefits, limitations, and potential risks of pediatric respirators. Ensuring informed decision-making prevents misuse and fosters trust in regulatory guidelines (World Health Organization, 2021, McDonald et.al., 2020). Additionally, privacy and data protection, including anthropometric data capture and data collected during trials, are crucial considerations. Some advanced respirators incorporate sensors or monitoring technologies, which necessitate ethical guidelines addressing data collection, storage, and user privacy concerns to prevent unauthorized access or exploitation (European Data Protection Board, 2022).

RPD manufacturers should adhere to fair labor practices, avoiding exploitative working conditions or environmental harm. Ethical sourcing of materials and responsible production methods are essential to maintaining consumer trust (International Labour Organization, 2023). Furthermore, regulations should ensure that pediatric respirators are accessible to vulnerable populations, including children in low-income communities and those with disabilities. Policy interventions should address market-driven disparities (UNICEF, 2022).

It is also critical to respect cultural preferences, including considerations for facial coverings in different communities. Aligning protective devices with cultural norms can improve adoption rates (CDC, 2025).

Another point of importance is the environmental impact. FFRs contribute to waste accumulation, so ethical considerations should include sustainable production, biodegradable materials, and recycling programs to minimize environmental harm (United Nations Environment Programme, 2023). Sustainability in pediatric RPD design should prioritize environmental responsibility. One approach is to utilize biodegradable materials, which can significantly reduce the ecological footprint of these devices. Additionally, incorporating eco-friendly substances and advocating for responsible disposal methods in pediatric respirators can further enhance sustainability. Another key aspect is the development of reusable pediatric respirators equipped with modular, replaceable filtration units and clear maintenance and use guidance ensuring that the devices can be used multiple times.

Transparent reporting on production processes and supply chains enhances consumer trust and regulatory oversight, mitigating risks associated with substandard manufacturing conditions (International Labour Organization, 2023). Moreover, governments and manufacturers should maintain transparency in regulatory approvals to ensure that pediatric respirators meet safety standards without undue influence from commercial interests (World Health Organization, 2021).

Children's respiratory protection has historically received insufficient attention in strategic public health planning. One significant barrier is the just allocation of limited resources. As McDonald *et al.* (2020) argue, ethical considerations must inform how public health interventions are prioritized, especially when vulnerable populations such as children are involved. Ensuring equitable access to pediatric respiratory protection involves not only producing suitable devices but also addressing disparities in awareness, education, distribution infrastructure, and price sensitivity across socioeconomic and geographic divides.

McDonald *et al.* (2020) and the FACE-UP team have been actively researching the ethical and policy challenges related to the public's (children and adult) use of respiratory protection. Their work underscores the critical need for an ethical framework that guides decision-making in this area. Their ongoing research highlights gaps in regulatory policies, the need for pediatric-specific certification standards, and the importance of inclusive policymaking that considers the rights and needs of children in emergency preparedness and health system planning.

While governments must weigh competing health priorities, the provision of effective respiratory protection for children, especially in the face of respiratory pandemics and air quality crises, should be recognized as a foundational element of public health preparedness. Through ethical resource allocation and coordinated action, it is possible to close the protection gap for children and improve long-term public health resilience.

ADDITIONAL GAPS IN RESEARCH AND STANDARDS

There are several notable gaps in pediatric respiratory protection research and development. One significant issue is the lack of data concerning children's facial measurements across various demographics and ages. Differences in facial shape and size among different populations complicate the creation of standardized respirator designs (Nemeth *et al.*, 2025). Another gap pertains to the lack of data surrounding respirator fit in children. Ensuring that these devices provide a snug fit without compromising breathability remains a key obstacle, according to Holm (2022). Additionally, there is a dearth of information on physiological effects experienced by children during respirator wear (both acute and long duration), as well as children's comfort and tolerability of different RPDs.

Further gaps include the absence of standardized pediatric-specific testing protocols, which limit the ability to ensure consistent and reliable performance across different designs and manufacturers. Research is also limited regarding behavioral aspects of respirator use in children, such as compliance, correct usage, and the tendency to adjust or remove the respirator due to discomfort, fear, or misunderstanding.

Additionally, child- and carer-appropriate seal check procedures should be informed by data. Research is needed on: a) which modified seal check procedures are effective for children and their carers; and b) how those procedures should be described in manufacturer user instructions. Similar research on the effectiveness and understandability of written instructions and education to support children and carers in correctly putting on respirators would also be valuable.

Moreover, minimal study has been conducted on communication barriers created by respirators, including challenges with speech clarity and interpreting facial expressions, which are crucial for children who rely on adult instructions and emotional cues (Nobrega *et al.*, 2020). There is also scarce research on the impact of respirator use on learning and cognitive function, particularly during prolonged use in educational settings.

The compatibility of respirators with other equipment or medical devices - such as eyeglasses, hearing aids, orthodontic appliances, head coverings, and hair styles and accessories - is another area that remains underexplored. Lastly, there is insufficient research into socio-cultural context and equity considerations, including differences in acceptance, accessibility, and effective use of respirators among diverse pediatric populations. Addressing these gaps is essential for advancing effective pediatric respiratory protection.

RECOMMENDATIONS AND NEXT STEPS

Advancing pediatric respirator standards require global cooperation. New pediatric RPD standards can build on the adult occupational standard model, but further evidence collection and testing protocols incorporating child-specific physiological and ergonomic considerations are needed. Given the differences inherent in public health guidance - as opposed to enforceable workplace standards - educational and cultural factors will need to especially be considered in the development of the framework for use of children's respirators.

Based on current research and expert guidance, the following performance and design criteria are recommended for consideration by standards developers for children's respirators intended for protection against particulate matter and airborne pathogens:

- Filtration Efficiency

  Pediatric respirators should achieve a minimum of 95% filtration efficiency for particles ≥0.3 μm in diameter, which is consistent with recommendations for adults (EPA, 2018; WHO, 2023; UNICEF, n.d.[b]), but at child-specific flow rates.

- Breathability

  The acceptable pressure drop in children's respirators should be low enough to minimize breathing resistance, but high enough to maintain effective filtration. Pediatric respirators should have breathing resistance pressure drop less than 50 pascals (Pa) at child-specific flow rates (Verma et.al., 2019; Hasni, 2024; Gudgin Dickson *et al.*, 2025).

- Fit Capability (including size and shape)

  Research activities are needed to establish a fit capability requirement including developing robust anthropometric panels, generating evidence to support appropriate fit capability criteria that could be evaluated in a laboratory setting, and leveraging existing laboratory methods.

- Comfort and Acceptability

  Pediatric respirators should eliminate coarse elements, use ergonomic designs, prioritize hypoallergenic materials, design for visual appeal, ensure ease of use with intuitive features, enhance caregiver acceptability, and be accompanied by educational materials.

- Marking, Instructions for Use, Storage, and Shelf-life

  Pediatric respirators should incorporate pictorial guidance, use culturally appropriate instructions, integrate usability features (like earloop clips), and develop educational materials in multiple formats. Pediatric respirators should be designed to be stored in a range of conditions and include instructions on recommended storage conditions. Manufacturers should provide a shelf-life, and respirators need to be designed to accommodate various storage conditions.

- Reusability, Stability and Durability

  Pediatric respirators should ensure they are fully functional for their duration of use, they should be built with high quality materials, and inspection instructions - allowing the user to identify when a respirator is not going to be protective - e.g., when a strap is broken.

The next step in developing pediatric RPDs is to prioritize the creation of one or more global consensus standard(s), supported by robust evidence gathering, and research to fill identified gaps, to inform performance requirements, particularly around fit, breathability, and usability for children.

Effective implementation will require coordinated action among governments, manufacturers, and health agencies. Public-private partnerships should establish multi-stakeholder working groups to align design, testing, and distribution. Equitable access, especially in low- and middle-income countries, should be ensured through policy-driven subsidies, procurement strategies, and health system integration.

A report by UNICEF emphasizes the role of primary health care in achieving universal health coverage and highlights strategic partnerships between governments, manufacturers and health agencies to strengthen health systems (UNICEF, n.d. [c]). Strengthening supply chains, integrating community health workers, and implementing targeted policies can significantly enhance access to pediatric respiratory protection.

Advancing innovation is also critical. Research and development priorities include:

- Incorporating affordable, high-performance materials to improve breathability and filtration.
- Conducting large-scale usability, comfort and fit studies specifically with pediatric populations.
- Developing standardized training tailored to different literacy levels and cultural contexts.

Educational outreach, through both public health campaigns and digital platforms, should support correct use among caregivers and medical professionals. Embedding respirator education within broader pediatric respiratory health initiatives will further support safe and effective adoption.

ACKNOWLEDGEMENTS

Thanks to the attendees of the second ISRP - FACE-UP workshop for their contributions to discussions, which informed this paper. Full list of attendees: Nick Baxter, Dominic DeRubbio, Evan Floyd, Karen S. Galea, Stephanie Holm, Claire Horwell*, Reese Koehler, Stephanie Lynch, Nikki McCullough*, Will Mueller, Neil O'Regan, Margaret Sietsema, Simon Smith*, Christoph Thelen, Dan Warkander, Jane Whitelaw. Thanks to the additional note takers at the 2nd ISRP - FACE-UP workshop: Rachel Meach and Chandika Shrestha. *Chaired roundtable discussions.

Prior to submission for publication, the authors included an international consultation stage, to garner feedback on this paper. Thanks to the following for reviewing a draft of this paper:

Howard Cohen, Aaron Collins, Karen S Galea, Miranda Loh, Will Mueller, Jung-Kuen Park, Gabriele Troescher, Dan Warkander, Michael Williams

Funding statement

Factors Affecting Childhood Exposures to Urban Particulates (FACE-UP) was funded by a UKRI Collective Fund award under the Global Challenges Research Fund (UKRI GCRF grant reference: MR/T029897/1). The International Society for Respiratory Protection provided workshop funding.

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Appendix I. Topics Discussed during Workshop 2

Group 1: Designing respirators for children

1. How do we encourage better design of children's respirators?
    a. Better fit characteristics
    b. Better filtration efficiency
    c. Better design for acceptance
        i. Comfort
        ii. Low breathing resistance
        iii. Communication
    d. Reusability
    e. Simplicity
2. What information do we need about children?
    a. Face shape around the world
    b. Safety of respirators for children
    c. Disbenefits of respirators for children (e.g. impact to learning and communication)
    d. Ethical/cultural considerations?
3. What information do we need about respirators to effectively inform stakeholders of the appropriate path forward in the development of respirators for children?
    a. Who collects this data?
    b. How do we encourage the collection of this information?
    c. Who are the major stakeholders?

Group 2: Supply chains, access and affordability of children's respirators

4. How do we educate on how respirators can reduce particulate exposure and their efficacy? (not including poor fit of some products currently on the market)
5. Would better education drive demand? Could demand drive innovation?
6. How can it be ensured that children's respirators are of high quality, i.e. certified, with high filter efficiency and good fitting characteristics.
7. What would it take to increase supply and decrease cost, globally? (demand essentially driven by regulation)
8. How can we increase access in low and middle income countries?

Group 3: Standards and regulations for children's respirators

9. What standard information is already available/in development?
10. What sort of standard is most appropriate?
    a. What would the scope of such a standard be?
        i. Is it a performance standard?
        ii. Does it include selection and use?
        iii. What is the intended use/applicability?
        iv. What age groups?
    b. How do we develop it?
11. Do we need harmonization, globally? If so, how/in what way?
12. What policies can countries do to spot insufficient devices coming to market and to stop false claims by manufacturers?

Appendix II. Example Protocols for Fit Testing Children

Modified Protocol for unassisted fit testing child respirators

(3M Personal Communication, 2025)

- Subjects are novice users - no training on how to use a respirator, have used a respirator fewer than 5 times in the past year, preferably have never undergone a fit test
- Subjects are not coached on correct use. They are given the user instructions and packaging as references and are asked to put on the respirator to the best of their ability.
- Study staff must not guide or correct the donning of the respirator.
- Study staff must not direct participants to read the user instructions or urge participants to “read more” or “read more closely” the references provided.
- The child subject’s parents, guardian or responsible adult must be present and should assist the child in donning.
- If the respirator slides off the subject’s face during the fit test, the test should be stopped, the subject should re-don the respirator, and the test should be re-started from the beginning.

Protocol for fit testing child respirators

Modified Ambient Aerosol CNC Quantitative Fit Testing Protocol for Filtering Facepiece Respirators (OSHA (c), App A, Table A-1).

Exercises[1]	Exercise procedure	Measurement procedure
Bending Over	The test subject shall bend at the waist, as if going to touch his/her toes for 50 seconds and inhale 2 times at the bottom2	A 20 second ambient sample, followed by a 30 second mask sample.
Talking	The test subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor for 30 seconds. He/she will either read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song	A 30 second mask sample.
Head Side-to-Side	The test subject shall stand in place, slowly turning his/her head from side to side for 30 seconds and inhale 2 times at each extreme2	A 30 second mask sample.
Head Up-and-Down	The test subject shall stand in place, slowly moving his/her head up and down for 39 seconds and inhale 2 times at each extreme[2]	A 30 second mask sample followed by a 9 second ambient sample.

[1]Exercises are listed in the order in which they are to be administered.
[2]It is optional for test subjects to take additional breaths at other times during this exercise.

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A Standards Organization Document:
American National Standards Institute. (2015) *American National Standard Practices for Respiratory Protection*. American National Standards Institute, Inc., New York, NY. ANSI Z88.2.
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