CleanSpace®
RESPIRATORS

EVERY BREATH COUNTS

EFFECTIVE RESPIRATORY PROTECTION IN THE CONTEMPORARY WORKPLACE

A REAL-TIME STUDY OF WORKPLACE RESPIRATORY PROTECTION ON CLEAN SHAVEN STAFF AND THOSE WITH FACIAL HAIR WEARING A CLOSE-FITTING PAPR SYSTEM

SYNOPSIS

Workers exposed to airborne hazards such as silica, wildfire smoke, coal, welding fumes (Chromium 6), and COVID-19 could be afforded high level protection by wearing close-fitting powered air purifying respirators (PAPRs) over widely used negative pressure masks.[1,2,3]

This study indicates an advanced close-fitting PAPR system can reliably provide high level protection during typical workplace duties at moderate to high intensity levels, for both clean shaven subjects and those with facial hair.

A white paper for management of occupational respiratory hazards prepared by CleanSpace® Technology Pty Ltd, developer and manufacturer of CleanSpace respirator solutions.

PAPR systems offer users and employers superior, reliable personal safety and protection advantages over negative pressure masks.[4,5] Loose and close-fitting styled PAPR systems are positive pressure devices which do not rely on the mask being sealed to the face to provide protection. Positive pressure active airflow works, despite mask leaks, to reliably prevent entry of contaminated air.[4,5]

In addition to reliable high protection, positive airflow eliminates breathing resistance, heat, fogging and the need for tightly adjusted and uncomfortable face pieces - thus benefiting staff productivity and compliance.[6]

In many work environments, employers are unable to practically implement high performing respiratory protective equipment (RPE) as part of their respiratory programs as traditional belt-mounted hood PAPRs are complex and slow to don, cannot be stored/carried/worn in mobile or remote work and are difficult to clean/disinfect in clinical settings.[1]

In the last decade, close-fitting PAPR technology has greatly advanced. Modern, lightweight, compact PAPRs (with no belts or hoses) are now commercially available for a range of industrial and healthcare sectors. Employers and their staff, who are conducting typical tasks (walking, bending, talking) that demand easy and fast donning, free movement, access to tight spaces or sitting, would benefit from the advantages of these modern PAPR systems.[1]

Despite these benefits, current standards governing selection and use of respiratory protection equipment (RPE) recommend fit testing for close fitting respirators – and these same standards also preclude the use of close fitting respirators for wearers with facial hair.[3,7,8,9,10]

This study aims to support consideration for adopting a more practical approach to guidelines governing close-fitting PAPR use to align with loose fitting PAPR guidelines, specifically no requirements for fit testing and use by wearers with facial hair. The work also serves as a feasibility study on the equipment and the protocol used for real-time, onsite workplace protection factors (WPF) data collection. The protocol enabled the WPF data to be compared with a controlled standard quantitative fit testing following the OSHA standards. The principles of the study are taken from two published articles by Clayton et al.[11,12]

By measuring workplace protection offered by a close-fitting PAPR in staff with and without facial hair while performing typical work tasks, this original investigation provides a valuable measure of the level and consistency of protection for work in real time.

RPE is not protective if systems cannot be adopted or used correctly.[1,13] Modern small PAPR systems are a practical high protection solution that enables workplaces to upgrade from disposable negative pressure masks and improve staff safety.

The results of this study demonstrate that a modern PAPR system, CleanSpace™ PAPR, can deliver consistent high protection levels for workers who are clean shaven and those with facial hair, undertaking typical tasks at moderate to high exertion levels.

Fig 1. PAPR systems are recommended for workplaces where there is high risk of hazardous airborne contaminants.

Fig 2. A mine worker dons a PAPR system prior to going underground.

INTRODUCTION

RPE – PERSONAL DEFENSE AGAINST AIRBORNE HAZARDS

For many workplaces and the tasks undertaken, exposure to airborne contaminants such as silica, wildfire smoke, coal, welding fumes and COVID-19 poses a risk for development of acute and long-term health issues such as asthma, COPD, cancer or infections.[12] In some cases, hazards are dose-dependent, while in others, even limited exposure can lead to life-threatening disease.[1,2,3]

When the health and safety of staff is at risk, it is imperative to have controls in place. In the workplace, guidelines, standards and regulations direct employers and employees to ensure a safe work environment.

In many workplaces and tasks, exposure to contaminants cannot be managed with engineering controls alone. Examples include tasks undertaken in new or unfamiliar sites (contract work and mobile teams), remote locations (mine operations), or situations where workers must be located close to an airborne contaminant source (patient care, hard rock cutting etc).

After putting engineering measures in place, managing remaining hazards requires a program for use of personal protective equipment.[7,8,10,13]

RPE SELECTION

When selected and used appropriately, workplace RPE significantly reduces exposure to occupational hazards.[10,17] Several environmental considerations are involved in selecting appropriate RPE:

- Type of airborne contaminants
- Work tasks undertaken
- Compatibility of other PPE used
- Environmental setting: tight spaces, temperatures, working at height, clinical or intrinsically safe zone
- Wearer health or medical conditions.

Due to the importance of RPE selection, guidelines, standards and regulations advise the type, fit and rated level of protection. In Australia (where this study was conducted), the Standards AS/NZS 1716 outline the level of protection rating is "according to the assigned protection factor (APF), which is the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program."[7]

The standards also state that the choice of respirator must correspond to the type of hazard. A sizable range of respirators, face pieces and filters are available specifically designed to handle contaminants in various forms – particles, gases, or vapours.[3,4,5,9]

NEGATIVE PRESSURE RESPIRATORS

Negative pressure masks include disposable N95/FFP2 and reusable elastomeric respirators.

Although simple and consequently widely used, there are considerable risks associated with disposable respirators. As a result, guidelines provide they are intended "only for low hazard levels" and protection against particulates only.[3]

Serious disadvantages with the use of negative pressure masks include breathing resistance, heat stress, fogging of eye wear and wearers with medical conditions (respiratory, cardiac, etc) may be at risk or unable to use negative pressure respirators.[1,11 14,15]

Furthermore, negative pressure respirators require a continuous, reliable seal between the mask and face to provide protection. These devices are considered tight or close-fitting RPE. Wearers with facial hair cannot achieve a seal and are advised against using them.[3,5,7] In other cases, there are a proportion of workers who, due to face shape or size, cannot achieve a seal in negative pressure masks.

In the case of disposable masks, that are single use – these masks are associated with significant waste and environmental contamination.[18]

As the world shifts to a sustainable economy, workplaces will be better served with reusable solutions.[16]

POSITIVE PRESSURE RESPIRATORS

PAPRs work through positive mask air pressure to provide significantly higher protection that does not rely on mask seal.

Where particulates are a concern, PAPR systems also offer high-efficiency particulate air (HEPA) rated filters (similar filtration levels to HVAC systems) which must meet or exceed the certification specifications of 99.97% filtration efficiency for particulates 0.3 micron or above.[5,8]

Like elastomeric negative pressure masks, PAPRs have carbon filters which can be used with a range of common and high-risk gas and vapour hazards.[17] The positive filtered airflow eliminates heat stress, mask fatigue and fogging by flushing heat, moisture and CO_2 from the mask.

PAPRs provide one of the highest levels of workplace RPE protection.[3,5,7]

PAPRs can be used in a wide range of applications and settings to promote productivity, compliance and staff confidence in their RPE. High performing PAPRs are the gold standard for protection in many industrial and healthcare settings.[3,5,7]

However, traditional PAPR design is associated with large belt mounted or head top battery/motor packs requiring complex assembly, donning/doffing and cleaning. Despite the high level and reliable protection of PAPRs, this complexity and issues with practical use in the everyday workplace has limited their adoption and use.[1]

MODERN PAPR TECHNOLOGY

Advances in PAPR technology have facilitated lighter weight, more compact powered systems. Through miniaturisation and air pressure controls, modern PAPR devices offer the convenience of a negative pressure mask (ease of donning/doffing, lightweight, compact design) with the reliably high protection of a powered respirator, across industrial and healthcare applications.

Advanced close fitting PAPR design leaves the body free of belts and hoses. Lightweight (less than 500g/1.1lb) PAPRs typically have few parts and enable fast and easy donning.

Fig 3. Lightweight PAPRs, with no belts or hoses, offer ergonomic and practical use advantages in a range of workplace settings.

Modern, lightweight, close-fitting PAPRs, like the CleanSpace respirators used in this study, enable practical adoption of high positive pressure HEPA protection and have changed the landscape of workplace respiratory protection – offering a practical and cost-effective solution for employers looking to upgrade from disposable masks to PAPR systems.

Unlike constant flow PAPRs, this version of the modern PAPR, CleanSpace respirators, offers breath responsive innovation that enables the system to dynamically (in real time) adapts to match the wearer's respiratory rate.

The advantages of a sophisticated breath responsive respirator include optimised filter and battery use to support smaller and lighter parts. And an improved user experience – avoids constant high flow rates that dry eyes and have high noise levels. With respect to the breath-responsive respirator technology, airflow is delivered via close fitting face pieces.

> Modern PAPR technology creates a comfortable and effortless RPE wearing experience, promoting higher compliance.

RESPIRATORY STANDARDS FALL BEHIND TECHNOLOGY INNOVATIONS

All certified PAPRs, including modern breath responsive PAPRs with close fitting face pieces are tested and certified as positive pressure respirators that create a superior protective environment by preventing inward mask leakage.[3,5,7,8]

However existing standards for close-fitting PAPRs, impose the same guidance for mask fitting and facial hair limitations as those for negative pressure masks (i.e. N95, FFP2 or elastomeric). Specifically, the standards for close-fitting PAPRs require fit testing and indicate these devices cannot be used by people with facial hair.[3,7,8]

> By failing to account for advances in technology, current respiratory protection standard requirements limit use of this type of close-fitting PAPR.

CURRENT STANDARDS FOR FACIAL HAIR AND FIT TESTING INADVERTENTLY SUPPORT UNSAFE WORK PRACTICES

Loose-fitting PAPRs hood systems do not require fit testing and are recommended for wearers with facial hair. Loose-fitting PAPRs are restrictive and impractical in many workplaces, potentially introducing new hazards with their bulk and complexity. Work applications and tasks that demand frequent or fast RPE donning, free movement or sitting preclude use of loose-fitting hood PAPRs.[1] The belts and hoses making up these systems are an impediment to clinical care and ambulance/ emergency teams where disinfection, dynamic tasks and driving are required. In these circumstances, a small, protective PAPR with few parts and free of hoses and belts makes it compatible with other PPE and facilitates easy integration into workflows to safeguard staff.

Anecdotally, employers who invest in large hooded PAPR systems have observed that the complex parts (which increase assembly and donning time) lead to their underuse, because staff (when able to) opt for fast and simple masks or nothing at all – even those with facial hair who will have no protection as a result.

Alternatively, facilities that select disposable masks (for the ease of use and simplicity) as their RPE, exclude or prevent staff who have facial hair for religious or other reasons from being able to do their jobs safely. Practically, where loose fitting PAPRs are used alongside disposable masks, workers (even those with facial hair) may demonstrate intentional non-compliance by choosing the simple, fast option.

The current restrictions on close-fitting PAPRs mean modern high performing respirators are unavailable to staff with facial hair. By failing to account for the technology behind them, current respiratory protection standards requirements narrow the use of PAPRs and therefore the necessary adoption of high protection. In this way, global protection standards have fallen behind equipment advances.

The gap between existing standards and innovations in RPE technology potentially reduces adoption of the safest options available and holds employers back from investing to improve their workplace respiratory protection programs.

Fig 4. Healthcare has accelerated adoption and use of high respiratory protection to PAPRs to manage airborne pathogens.

Standards require wearers of close-fitting devices to be fit tested before use. Quantitative fit testing, such as tests conducted with the TSI PortaCount®, measures total inward leakage (TIL) into the mask. Wearers with facial hair are advised against using close-fitting respiratory protection devices due to their inability to achieve a face seal and in the case of negative pressure masks, inward leakage.[3,5,7]

While mask seal is essential for wearer protection with negative pressure masks (disposables and reusable elastomerics), PAPRs (both loose-fitting and close-fitting) are positive pressure systems which do not rely on a face seal for protection.[4,5,17]

The study outlined in this paper measured the fit factors (FF), workplace protection factors (WPF) and exertion levels in staff with and without facial hair wearing a close-fitting CleanSpace PAPR while performing typical work duties. Equipment was adapted so WPF could be measured in real time on the job site, while performing typical tasks involving moderate to high exertion levels.[11,12]

Under the OSHA standard fit testing protocol, FF were recorded as a control to determine mask leakage (TIL) in 'Power On' and 'Power Off' device mode.[3,18]

TIL measures contaminant levels in the mask compared to those in ambient air and is considered the gold standard for testing respiratory protection level.[4]

This study also examined the feasibility of the equipment and protocol for measuring and comparing levels of protection in real time in a variety of workplace settings. It supports consideration of a more practical approach to guidelines governing close-fitting PAPR use, namely fit testing and use in wearers with facial hair.

> This study aims to support consideration for a more practical approach to the guidelines governing close-fitting PAPR use, specifically fit testing and use in wearers with facial hair.

Fig 5. PAPR systems incorporate face and eye protection and need to be compatible with other PPE.

METHODOLOGY

Twelve workers in three independent workplace sites participated in the study. Sites included a power plant, hard rock quarry and stonemason operations site. All participants were required to undertake their normal work duties during the study.

The study protocol was established based on principles taken from published articles by Clayton et al. (2012 and 2013) outlining a methodology to standardise the measurement of real-time respiratory protection in the workplace.[11,12] The protocol was also designed to assess the impact of facial hair and typical work tasks (walking, talking, bending) on the mask TIL and protection levels afforded by the PAPR in 'Power On' mode.

Standard quantitative fit tests, using the OSHA protocol (in 'Power Off'), were conducted before and after work sessions to test mask leak (TIL) and were used as a control.[19] An additional fit test was conducted in 'Power On' mode prior to the work sessions to measure the baseline protection in a controlled and standard environment. In total each participant underwent three quantitative fit tests.

The study sought to measure and confirm exertion levels during the work sessions while performing normal work duties, including walking, talking, lifting and bending, as required at each worksite. To assess repeatability, each subject undertook two 25-minute work sessions. Between work sessions, participants were required to remove their masks, have a five-minute break and don their mask to start their second work session. Participants were permitted to adjust their respirators themselves, if needed, as they normally would, in their typical workday. Participants followed the protocol below:

1. Quantitative fit test 'Power-Off'
2. Quantitative fit test 'Power-On'
3. Work session (25 min) – 1
4. Doff, 5 min break
5. Work session (25 min) – 2
6. Quantitative fit test 'Power-Off'

Common work task activities (such as bending, head turning, talking and heavy breathing) can challenge the mask seal. For this study, in addition to fit testing, work exertion rates were recorded by activity monitors and classified according to ISO 8996:2004 to account for inhalation levels (physical exertion) related to work duties. Job tasks were recorded by observation, photographs, videos and interviews. Work exertion levels across the three sites ranged from moderate to high.

The study was conducted during the summer season. Quantitative fit testing was done in a temperature-controlled room located outside the contaminated work areas. The work sessions were conducted in the operation sites where participants were normally required to wear respiratory equipment. Ambient temperatures on the site during the work sessions ranged from 20 – 31 °C (68 – 88 F).

EQUIPMENT AND MATERIALS

All participants wore a modern breath responsive close-fitting PAPR with either a half or full-face mask, CleanSpace™ HALO fitted with HEPA particulate filters (CleanSpace Technology Pty, Ltd, Sydney Australia). Sites selected were using modern PAPR respirators as part of their Respiratory Protection Programs. Study participants were familiar with the CleanSpace PAPRs, used in this study. They had previously received mask fitting, device training and were regular users of the respirators for a minimum of six months prior to study commencement. Subjects wore the mask size previously assigned to them following fitting and testing.

Quantitative fit testing was performed using a TSI Portacount under the OSHA standard. For the work sessions, the TSI Portacount device with battery was fitted into a backpack and connected to the mask of the PAPR system. TSI PortaCount equipment (TSI, Shoreview USA) was adapted to operate in a backpack carried by study participants. The PortaCount recorded mask and ambient particle concentrations. Using standard definitions (see below), WPF data was collected in real-time.

Commercially available activity/heart rate monitors (Fitbit Alta HR, San Francisco, USA) were worn during the work sessions.

Of the twelve participants, three were clean shaven and nine had facial hair ranging from heavy stubble to full beards. For the purpose of analysing and presenting the results, the participants' results were divided into Cohort 1 ('clean shaven') and Cohort 2 ('facial hair'). Each site had at least one participant who was clean shaven.

Fig 6-10. A sample of the study participants who demonstrated varying levels of facial hair.

DEFINITIONS:

Fit Factor (FF): This study measured the quantitative fit factor (QNFF) – the fit factor established during a quantitative fit test for a specific close-fitting respirator in a specific individual. It represents the contaminant concentration outside the respirator (Co) divided by the contaminant concentration inside the respirator (Ci) in a controlled environment. QNFF was measured with the TSI PortaCount according to the OSHA protocol. A FF equal to or greater than 100 for close-fitting half facepieces, or equal to or greater than 500 for close-fitting full facepieces, indicates the fit test has been passed with that respirator.[19,20]

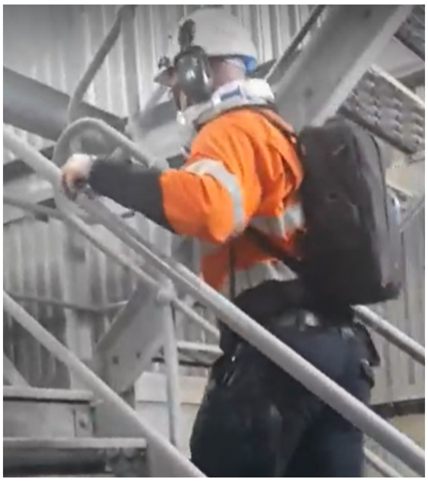
Total Inward Leaking (TIL): This is an estimate of the performance of a respirator, measured as the leakage of contaminants through the filter media, the face seal interface and the exhalation valve of respiratory protective devices under laboratory conditions. It is the inverse of the FF.[20,21]

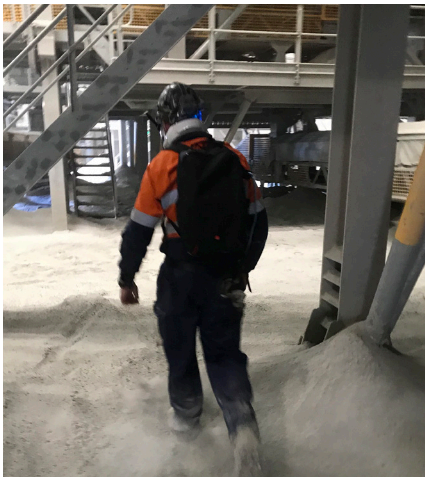
Workplace Protection Factor (WPF): A measure of the protection provided in the workplace, under the conditions of that workplace, by a properly selected, fit-tested and functioning respirator while it is correctly worn and used. WPF is a direct measurement of a respirator's performance in a specific work environment. It represents the workplace contaminant concentration outside the respirator (Co) divided by the contaminant concentration inside the respirator (Ci). Co and Ci must be measured simultaneously, only while the respirator is properly worn and used during normal work activities.[7,10,20]

Workplace Protection Factor Study: A study conducted under actual conditions of use in the workplace, that measures the protection provided by a properly selected, fit tested, and functioning respirator, when the respirator is worn correctly and used as part of a comprehensive respirator program that is in compliance with OSHA's Respiratory Protection standard at 29 CFR 1910.134. Measurements of Co and Ci are obtained only while the respirator is being worn during performance of normal work tasks (i.e. samples are not collected when the respirator is not being worn). As the degree of protection afforded by the respirator increases, the WPF increases.[7,10,20]

Fig 11-16. During work sessions, participants conducted typical work tasks while wearing the TSI Portacount in a backpack and the close-fitting PAPR.








RESULTS

The study successfully captured results from 12 participants who completed the full protocol. There were 3 participants (results not published in this paper), where due to technical errors, a full data set was not captured. On the whole, the TSI Portacount was successfully adapted to a mobile and connected system, was reliable and participants did not report they were materially impacted by the addition of the backpack to their typical tasks.

Results have been divided into participants clean shaven (Cohort-1, 3) and those with facial hair (Cohort-2, 9).

FIT TESTING PRIOR TO WORK SESSIONS

All subjects, including those with facial hair, passed the fit test in 'Power-On'. The fit test conducted in 'Power-Off' confirmed the clean-shaven subjects achieved mask seal (FF>500) and the subjects with facial hair failed the mask fit test (FF < 100) which indicated mask leak.

Table 1. Results for fit tests for Cohort 1 and 2 prior to work sessions and for reference after the work sessions.

Fit Test (FF) Average (min-max)	Participants	Fit Test Power On	Fit Test Power Off	Fit Test Power Off (After work sessions)
Cohort 1 (Clean Shaven)	3	12,945 (4,642 – 28,622)	9,123 (1,538 – 21,496)	3,386 (560 - 5,571)
Cohort 2 (Facial Hair)	9	15791 (1,321 - 39,502)	8 (1 – 24)	16 (2 – 38)

WORK SESSIONS - ACTIVITIES AND WORK EXERTION LEVELS

Activities recorded during the work sessions included walking, climbing stairs and bending to inspect equipment. At the stone handling site, activities also included moving stone by hand, bonding and grinding.

The level of exertion, based on participants' heart rates and body weights, ranged from moderate to very high according to ISO 8996. Heart rates (HR) for several participants during work session 2 at one site were not recorded due to an error. Video and observation confirmed that the participants undertook similar work to the first work session. Based on HR data, there was no difference in activity level between sites or workers with facial hair or clean shaven.

Table 2. Results for Heart Rate (BPM) for participants during the two work sessions.

Heart Rate (BPM) Average (min-max)	Participants	Work Session 1	Work Session 2
Cohort 1 (Clean Shaven)	3	103 (77-127)	Data not collected
Cohort 2 (Facial Hair)	9	97 (69-136)	103 (75-149)

WORK SESSIONS - WORKPLACE PROTECTION FACTORS (WPF)

Work sessions were conducted with the PAPR working as intended ('Power On' mode). Due to the data collection, every alternate minute, at times the testing reported very high WPF data (>100,000). The TSI PortaCount detection threshold is in the range 0.1 to 0.5 particles per cc. Ambient concentrations measured during the study were on average 10,000 particles per cc. An FF above 100,000 would suggest very low/no particles detected in the mask. The very high FF of >100,000 distorted the data, resulting in very high medians. For this reason, outliers (FF >100,000) were removed for the purpose of final data analysis. Out of 492 minutes sampled, 15 FF 100,000 data points were revised.

At each of the three sites, average ambient particulate concentration levels recorded by the PortaCount during the two work sessions were: Site 1: 16,479; Site 2: 17,595; Site 3:10,720.

Table 3. WPF results, as measured by the TSI Portacount backpack, for the participants for the two work sessions.

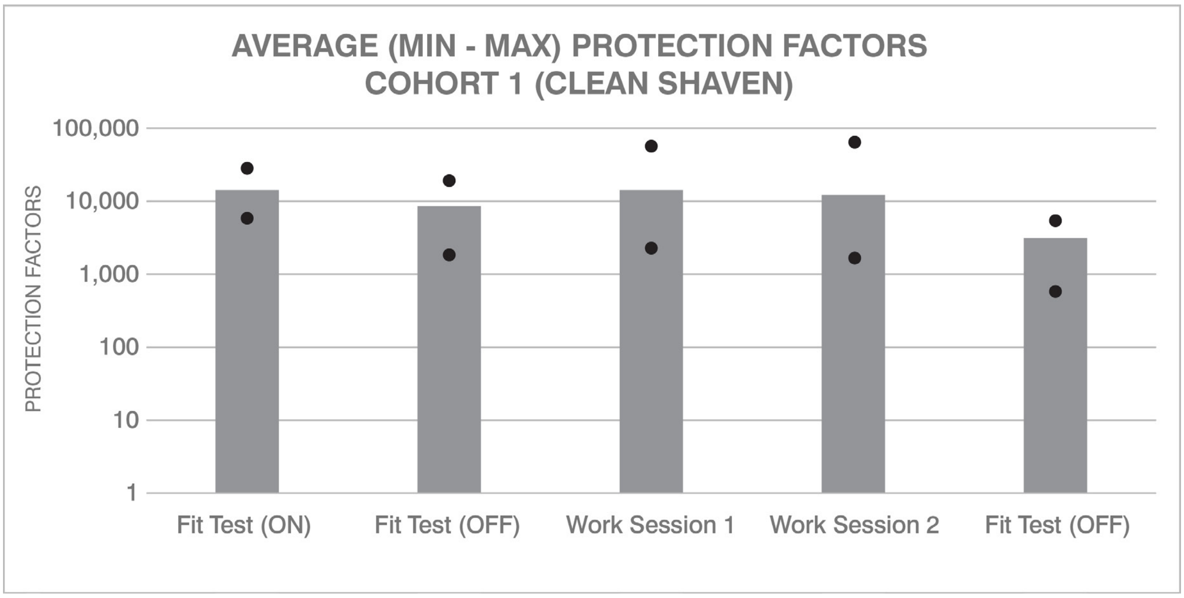
Average WPF	Participants	Work Session 1	Work Session 2
Cohort 1 (Clean Shaven)	3	11,733	11,485
Cohort 2 (Facial Hair)	9	6,089	6,870

The 5th percentile WPF for combined work sessions was Cohort 1 (clean shaven) 3,942 and for Cohort 2 (facial hair) was 1,309.

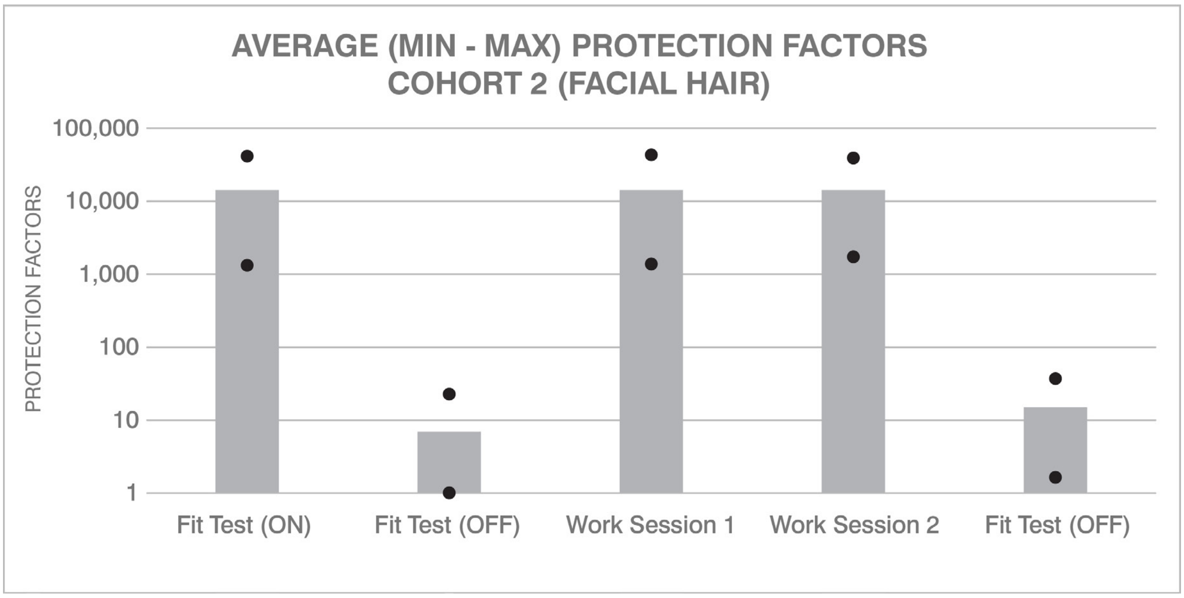
FIT TESTING FOLLOWING THE WORK SESSIONS

A final fit test ('Power Off' mode) demonstrated participants who were clean shaven returned a pass (>500) indicating they maintain their mask seal through the concurrent work sessions and the re-donning and fitting of their masks between work sessions. In comparison, all participants with facial hair failed their fit test (in 'Power Off' mode) indicating mask leakage in 'Power Off' mode.

Graph 1.1 Averages (min-max) for the fit tests and work sessions for Cohort 1 (clean shaven)



Graph 1.2 Averages (min-max) for the fit tests and work sessions for Cohort 2 (facial hair)



The results of this study demonstrate consistently high levels of protection (FF average 8,000) provided by a positive pressure close fitting PAPR in the workplace while undertaking work tasks (walking, talking, bending and heavy exertion) that would typically challenge mask seal. The WPF and FF results from the participants with facial hair also demonstrated the high protection level (FF above 1,000) with the close-fitting PAPR in the 'Power On' fit test and throughout the study's two 25-minute work sessions.

DISCUSSION

The results of this study indicate an advanced close-fitting PAPR system can reliably provide high level protection during typical workplace duties at moderate to high intensity levels for clean shaven subjects and subjects with facial hair. The study also served as a feasibility test for a working model to measure real-time workplace respiratory protection levels of RPE.

The participants with facial hair (Cohort 2) demonstrated mask leak in 'Power Off' fit testing (in negative pressure). When the fit tests were conducted in 'Power On' mode, and importantly during work activity in the work sessions, they demonstrated high levels of protection (FF>1,000).

The study data supports the view that current standards do not accurately account for the advantages of approved modern RPE. Requirements for fit tests in negative pressure and restrictions on use with facial hair limit RPE options for employers and workers that could ensure a safer work environment.

For Cohort 1 and 2, fit testing under the OSHA protocol performed in operational mode ('Power On') resulted in data for the close fitting PAPRs reflecting protection levels significantly above those offered by negative pressure masks.

The close fitting PAPRs used in this study represent the advancements in respirator technology - delivering positive pressure, breath responsive HEPA filtered air in a lightweight (<500g/1.1lb) compact device.

These modern power units employ pressure sensors and proprietary algorithms that control the airflow and mask pressure to adapt in real time to the user's respiratory rate. The system is as dynamic as the wearer's breathing and able to respond to risks in drops in mask pressure including leaks. The system continually adjusts airflow to ensure the mask is always in positive pressure above ambient pressure to effectively prevent contaminated air entering the mask.

All powered positive pressure PAPRs are independently tested and approved only if the devices can meet or exceed the quantitative fit testing conducted under the Standards.[3,7,8]

Close fitting PAPRs are positive pressure and work to overcome any mask leak, the same way loose-fitting PAPRs work. PAPRs are designed to be used with the power on and the airflow active. Logically, where specific modern breath responsive close fitting PAPRs have NIOSH, EN12942 and AS/NZS 1716 certifications, then these systems are expected to consistently protect at high PAPR levels during normal work tasks.

Fig 17. Modern PAPRs are more versatile than hooded PAPRs – being compatible with a range of other PPE and able to be readily used in tight spaces.

Fig 18. An example of a modern lightweight PAPR system - CleanSpace PAPR with a silicone half mask.

CONCLUSION

The study provides reasonable justification for taking a more practical approach to standards governing close-fitting PAPR use with regards to fit testing and use in wearers with facial hair. Loose and close-fitting PAPRs are positive pressure devices, neither of which rely on the mask being sealed to the face to provide wearers with high level protection. Data from this study demonstrated high protection levels, suggesting fit testing and use with facial hair must be reconsidered in updated standards to reflect modern technology.

> Respiratory protection is essential to the health and productivity of workers at risk of exposure to airborne hazards.[13]

Common airborne contaminants in the industrial and healthcare sectors are at best irritants and at worst lethal. The industrial sector is associated with known carcinogens such as crystalline silica and the healthcare sector with life-threatening airborne viruses.[1,4]

Many operations inherently require staff to be active and moving in and out of contaminated areas. They also involve staff carrying out physically demanding tasks, in hot temperatures, over long shifts; or in remote or constantly changing locations. In today's world, teams can be working around the clock to meet care, productivity or efficiency targets. Traditionally, these challenges – along with mask fitting, training, and compliance – have been major barriers to effective PAPR respiratory protection. In these work environments, employers are unable to practically deploy traditional belt mounted hood PAPR – which are complex and slow to don, cannot be stored/carried/worn in mobile or remote work and are difficult to clean/disinfect in clinical settings.

Technological innovation has transformed the RPE landscape. Lightweight, compact and 'easy to use' PAPR systems, like CleanSpace PAPRs, offer employers a practical solution for high protection that workers can readily use in many environments. Changes to existing standards governing RPE use could give employers and staff access to these high level protection PAPRs and improve workplace safety.

> RPE is not protective if systems cannot be adopted or used correctly.[13]

INDUSTRY PARTNER CONTRIBUTORS

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DECLARATION OF CONFLICTING INTERESTS

This study was funded by CleanSpace Technology Pty Ltd. Mr Virr, Mr Cai and Dr Birrell are full time employees of and hold shares in CleanSpace Technology Pty Ltd, Sydney Australia. Dr Birrell is also a director of the Company.

REFERENCES

1 Centers for Disease Control and Prevention (CDC), Considerations for optimizing the supply of powered air-purifying respirators (PAPRs) for healthcare practitioners (HCP), Updated Nov. 3, 2020. https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/powered-air-purifying-respirators-strategy.html

2 The Use and Effectiveness of Powered Air Purifying Respirators in Health Care: Workshop Summary. Board on Health Sciences Policy; Institute of Medicine. Washington (DC): National Academies Press (US); 2015 May 7.

3 US Department of Labor: Occupational Safety and Health Administration (OSHA) standard 1910.134. Occupational Safety and Health Standards, Personal Protective Equipment, Respiratory Protection. https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134

4 US Department of Labor: Occupational Safety and Health Administration (OSHA), Assigned Protection Factors for the Revised Respiratory Protection Standard. https://www.osha.gov/sites/default/files/publications/3352-APF-respirators.pdf

5 National Institutes of Health (NIH), National Library of Medicine, Board on Health Sciences Policy; Institute of Medicine. The Use and Effectiveness of Powered Air Purifying Respirators in Health Care: Workshop Summary, Washington (DC): National Academies Press (US); 2015 May 7. https://www.ncbi.nlm.nih.gov/books/NBK294223/

6 Chong LS, Bundele A, Sumner J, Mukhopadhyay A, 2022. Advances in respiratory protective equipment: practical experiences of CleanSpace Halo by healthcare workers. Journal of Hospital Infection 124, 22 – 28.

7 AS/NZS 1715:2009 Selection, use and maintenance of respiratory protective equipment https://www.standards.org. au/standards-catalogue/sa-snz/publicsafety/sf-010/as-slash-nzs–1715- 2009

8 EN 12942 Respiratory protective devices - Power assisted filtering devices incorporating full face masks, half masks or quarter masks - Requirements, testing, marking. https://www.en-standard.eu/din-en-12942-respiratory-protective-devices-power-assisted-filtering-devices-incorporating-full-face-masks-half-masks-or-quarter-masks-requirements-testing-marking-includes-amendment-a1-2002-and-amendment-a2-2008/

9 ISO 16975-3:2017 Respiratory protective devices - Selection, use and maintenance Part 3: Fit-testing procedures. https://www.iso.org/standard/64513.html

10 Health and Safety Executive (HSE), Respiratory equipment at work. HSG53 (Fourth edition, published 2013). https://www.hse.gov.uk/pubns/priced/hsg53.pdf

11 Clayton, M, Rajan-Sithamparanadarajah, B, Vaughn, N 2012, Performance Studies on Respiratory Protective Devices in the Workplace – Part 1 Variation in Measures of Performance, Journal of the International Society for Respiratory Protection, Vol. 29 No

12 Clayton, M, Rajan-Sithamparanadarajah, B, Vaughn, N 2013 Performance Studies on Respiratory Protective Devices in the Workplace – Part 2 Towards a Unified Approach, Journal of the International Society for Respiratory Protection, Vol. 30 No. 1

13 Howie RM, Respiratory protective equipment, Occupational and Environmental Medicine 2005;62:423-428, https://oem.bmj.com/content/62/6/423

14 Tabah A., Ramanan M., Laupland K.B., Buetti N., Cortegiani A., Mellinghoff J. et al. Personal protective equipment and intensive care unit healthcare worker safety in the COVID-19 era (PPE-SAFE): an international survey.
J Crit Care. 2020; 59: 70-75

15 Bharatendu C, Ong JJY, Goh Y et al, 2020 Powered Air Purifying Respirator (PAPR) restores the N95 face mask induced cerebral hemodynamic alterations among Healthcare Workers during COVID-19 Outbreak. Journal Neurological Science 15, 417: 117078

16 Morgana S, Casentini B, Amalfitano S, 2021, Uncovering the release of micro-nanoplastics from disposable face masks at times of COVID-19. Journal of Hazardous Materials 419, 126507

17 US Department of Labor: Occupational Safety and Health Administration (OSHA), Respiratory Protection. https://www.osha.gov/respiratory-protection

18 World Health Organisation (WHO) Report, Global analysis of healthcare waste in the context of COVID-19: status, impacts and recommendations. 2022: https://www.who.int/publications/i/item/9789240039612

19 US Department of Labor: Occupational Safety and Health Administration (OSHA) standard 1910.134, Appendix A – Fit Testing Procedure (Mandatory), Part 1 – OSHA-Accepted Fit Test Protocols. https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134AppA

20 Janssen, L and Mckay, R New Terminology for Respiratory Protection, https://synergist.aiha.org/201604-new-terminology-for-respiratory-prote

21 Centers for Disease Control and Prevention (CDC), The National Institute for Occupational Safety and Health (NIOSH), Total Inward Leakage (TIL) for Respiratory Protective Devices, 2019 https://www.cdc.gov/niosh/data/datasets/rd-1011-2019-1/default.html

Fig 19. Modern PAPRs eliminate complex belts and hoses; and are easily donned and doffed.

CleanSpace®
RESPIRATORS

EVERY BREATH COUNTS

ABOUT CLEANSPACE TECHNOLOGY

CleanSpace is a Sydney-based designer and manufacturer of advanced and world leading respiratory protection solutions for industrial and healthcare settings. Founded by a team of biomedical engineers with experience in respiratory medicinal devices and a vision to modernise and revolutionise personal respiratory protection.

CleanSpace is passionate about continually improving health outcomes, workplace safety and standards of care. In the last 20 years, technology has driven unprecedented advances in medical equipment and transformed people's health. The team at CleanSpace have brought this experience and innovative approach to personal respiratory protection.

The Company continues to invest in cutting edge research and development programs that underpin leading differentiated designs and innovative solutions. CleanSpace's comprehensive range of approved products provide compelling employer and user benefits, namely, higher protection with improved compliance and productivity and significant cost efficiencies.

Every breath responsive CleanSpace PAPR is powered by the patented AirSensit™ technology. This platform incorporates proprietary technology featuring unique airflow/mask pressure control (through its motor/fan and algorithms), intuitive operating system and miniaturisation.

AirSensit™ technology makes CleanSpace devices the lightest and smallest PAPRs in the world and enables CleanSpace to reset industry best practice for respiratory protection.

Today, this technology has been adopted by thousands of healthcare and industry organisations including: mining, construction, quarrying, chemical, metal and pharmaceutical manufacturing in more than 36 countries.

CleanSpace technology is a true game changer and disrupter – bringing a new standard to respiratory protection that positively impacts the health and safety of people at risk of common airborne hazards.

CLEANSPACE TECHNOLOGY PTY LTD

For more information visit our website www.cleanspacetechnology.com or contact us on www.cleanspacetechnology.com/contact