

Use of CleanSpace PAPRs by workers with Facial Hair

MANUFACTURER'S STATEMENT

CleanSpace PAPRs are designed and certified to provide high - level respiratory protection. CleanSpace PAPR protection performance is not reliant on achieving a good mask seal. Annual fit testing and being clean shaven will improve a wearer's mask fit. However, these are not requirements that ensure a high level of wearer respiratory protection. Provided the wearer has been properly fitted (right sized mask, harness adjusted) and trained, CleanSpace PAPRs used correctly will provide a high level of protection for wearers with facial hair and in other circumstances that causes mask leak, e.g talking, high exertion and mask self-adjustments.

CleanSpace Technology prioritises a wearer's respiratory protection. PAPR systems provide a significantly higher and more reliable level of protection than negative pressure masks, e.g disposables or elastomerics. PAPRs are the gold standard solution for protection against workplace airborne hazards. This statement is designed to provide employers and wearers with a practical, high-performing PAPR solution (easy to use, cost effective) that improves their organisation's safety programs and risk management.

SUPPORTING INFORMATION

Respirator Guidelines

Guidelines for the selection and use of respiratory protection equipment were published prior to CleanSpace Technology being commercialised and at that time, close-fitting masks were equated with negative pressure (passive) masks.

- Guidelines for the use of close-fitting masks^{1,2,3} require annual fit testing and a requirement to be clean shaven as this sets the wearer to have a good mask seal to ensure good protection since a close-fitting passive mask without mask seal is not protective..
- Guidelines for the use of loose fitting/hood PAPRs^{1,2,3} confirm that positive pressure respirators provide high protection to wearers despite 'facepiece' leak as the positive pressure (through high airflow) actively prevents Total Inward Leakage (TIL). Therefore, Guidelines for loose fitting/hood PAPRs do not require fit testing or limitations for those with facial hair.

CleanSpace technology

CleanSpace respirators are a modern powered airflow system driven by a platform technology, AirSensit[®]. Developed by biomedical engineers with a deep expertise in respiratory medical devices, CleanSpace PAPRs are a breath-responsive system that responds in real-time to changes in mask pressure (at 100 Hz) to maintain a consistent and reliable positive mask pressure that prevents inward leakage.

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R E S P I R A T O R S

CleanSpace PAPRs use close fitting masks but do not rely on the mask to be sealed. The technology's ability to continuously monitor mask pressure, delivers high peak airflows (230l/min)⁴ and responds rapidly (100Hz)^{*} to changes in pressure means that CleanSpace's AirSensit[®] technology can reliably overcome a large range of mask leak to provide respiratory protection to the wearer.

** Motor control system samples mask pressure and adjusts motor speed at 100Hz. Actual system response is demonstrated by maintaining positive mask pressure at all times at end of NIOSH silica dust test (NIOSH procedures: TEB-APR-STP-0003, RCT-APRSTP-0025 and RCT-APR-STP-0065).*

Fit Testing in Power On vs Power Off

Some guidelines (USA and UK) have been interpreted to require fit testing only in negative pressure (power off mode). This is counter-intuitive for PAPRs. CleanSpace PAPRs, like all PAPR systems, are designed and instruct wearers to use in 'power on' mode (with the motor/ fan running and an active airflow). User Instructions outline steps to ensure there is -

- i. a charged battery,
- ii. the device is on and
- iii. there is the required airflow.

Similar to instructions for loose fitting PAPRs, the wearer is directed to leave the contaminated area if the power unit switches off during use. At no time are wearers directed to use CleanSpace PAPR in power off mode.

CleanSpace PAPRs' proven high protection

CleanSpace PAPR systems have been proven to maintain a high-level protection through positive mask pressure even with proven mask leak in a range of situations:

1. Independent certified laboratories (US, EU, UK, AU) conducting repeated testing over 12 years
2. Customer fit testing: nearly 300 industrial protection factor tests in power on mode
3. Workplace Protection Factor (WPF) Studies: Australia and UK.

CleanSpace Workplace Protection Factor (WPF) Studies: Australia and UK

CleanSpace has conducted two studies to measure the Workplace Protection Factors (WPFs) of workers wearing the CleanSpace PAPR systems (based on the methodology published by Clayton et al, 2012 and 2013)^{5,6}. The studies evaluated wearers in real work settings with typical daily tasks incorporating known challenges to mask seal such as self-donning, talking, high exertion and facial hair. The results of these studies confirmed that CleanSpace respirators consistently achieved reliable high protection factors (protection factors over 4,000) during typical workplace tasks with the known challenges to mask seal (Sources: [CleanSpace White Paper Workplace Protection Factors \(Australia 2020\)](#); and [CleanSpace Workplace Protection Factor Study UK 2023](#)).

CleanSpace Certifications

All CleanSpace PAPR systems have been successfully tested and approved as a close fitting PAPR for major international respiratory equipment regulations:

- NIOSH (USA)
- EN12942, CE Mark (Europe)
- AS/NZS 1715:2009 (Australia/NZ)

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R E S P I R A T O R S

The regulations require CleanSpace PAPR systems to be independently tested by certified laboratories. The Standards include tests for wearer protection and safety. NIOSH, EN12942 and AS/NZS1716 are recognised as the most stringent and highest level of respirator standards in the world. Under these standards, close fitting PAPRs are rated as the highest level of protection for air-purification respirators – including having a higher protection rating than disposable masks, elastomerics and loose fitting PAPRs.

References

- [1] AS/ NZS 1715:2009 Selection, use and maintenance of respiratory protective equipment (Published 06/02/2009),
- [2] 29 CFR 1910.134 Major Requirements Of OSHA's Respiratory Protection Standard 29 CFR 1910.134. Available at https://www.osha.gov/sites/default/files/training-library_major_requirements.pdf (accessed April 2023)
- [3] BS EN529:2005 Respiratory protection devices. Recommendations for selection, use, care and maintenance. Guidance document (Released 22/11/2005)
- [4] Results of internal testing Feb 2023: CleanSpace CST ULTRA or PRO, clean CST1004 filter, half mask, full battery (Data available on request)
- [5] Clayton M et al. 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. 1 (2012)
- [6] Clayton, M et al. 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 (2013)

For more information or if you have questions visit website:

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