

Use of CleanSpace PAPRs by workers with Facial Hair

MANUFACTURER'S STATEMENT

CleanSpace PAPRs are designed and certified to provide high-level respiratory protection when used in accordance with the manufacturer's instructions. 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 required to ensure a high level of wearer respiratory protection. Provided the wearer has been properly fitted (right sized mask, harness adjusted) and educated on the correct use of the equipment, 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 and high exertion.

PAPR systems provide a significantly higher and more reliable level of protection than negative pressure masks, e.g. disposables or elastomerics. This statement is designed to provide information to support the establishment of effective respiratory protective measures for all employees regardless of facial hair status.

SUPPORTING INFORMATION

Respirator Guidelines

Guidelines for the selection and use of respiratory protection equipment mostly date from before the commercialization of modern breath-responsive PAPRs.

- Guidelines for the use of close-fitting masks^{1,2,3} require annual fit testing and a requirement to be clean shaven.
- Guidelines for the use of loose fitting/hood PAPRs^{1,2,3} do not require fit testing or prohibit 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 100Hz) to maintain a consistent and reliable positive mask pressure that prevents inward mask leakage.

CleanSpace PAPRs use masks that sit close to the face but do not rely on the mask to be sealed. The technology's ability to continuously monitor mask pressure, deliver high peak airflows (usually over 200l/min)* and respond 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.

^{*} Results of internal testing Feb 2023: CleanSpace CST ULTRA or PRO, clean CST1004 filter, half mask, full battery (Data available on request)

^{**} 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 PAPRs in power off mode.

CleanSpace PAPRs' proven high protection

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

- 1. Independent certified laboratories (USA, 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)^{4,5}. 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 are certified to the following standards:

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

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.



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] 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)
- [5] 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)

This advice supersedes any previous statements (including in user instructions) from CleanSpace relating to facial hair and / or power-off fit testing. CleanSpace does not support power-off fit testing as it does not provide reliable information about the level of protection that will be provided by our PAPRs. CleanSpace recommends that a power-on, quantitative fit test to the OSHA protocol (or similar) be performed before a respirator is issued to an employee (and repeated if their facial hair status changes significantly). If that test results in a pass, and the respirator is checked and maintained as per the user instructions, the worker will be effectively protected during their work sessions, regardless of their facial hair status.

For more information or if you have questions visit website: www.cleanspacetechnology.com



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