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An inbuilt real-time check for mask fit and respirator protection for healthcare workers and emergency responders

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Background: In a respiratory protection program, the practice of mask Fit Testing for tight fitting respirators is best practice for most international respiratory protection standards. Fit Testing (either through a qualitative or quantitative method) is widely used as a determinant of how well the respirator protects the wearer and is conducted with new staff followed by annual re-testing. Many high-risk industries (healthcare, laboratories and emergency services) are required to report on their comprehensive annual Fit Testing programs with large remote or mobile teams. For these organizations fit testing can be a lengthy, costly and technically complex logistical process which restricts its use on a more frequent basis in the workplace. When conducted annually this leaves long periods during which the wearer's mask fit may change (facial hair or weight loss) resulting in a deterioration in protection offered by the respirator. Even without material facial changes, studies have reported high failure rates from day to day for passive masks (N95s) even when fitted by trained personnel. Practically, employers need an easier, faster and inexpensive daily check (between annual Fit Tests) to ensure staff are adequately protected or as an early alert for when staff may need to be re-fitted for their mask.

Methodology: CleanSpace Respirators were used in this study. CleanSpace is a new generation in respiratory protection incorporating the proprietary AirSensit[™] technology that monitors the mask pressure 100 times per second to maintain positive pressure during use. The system is dynamic and can detect minute changes in mask leak and resistance. Bluetooth[™] enabled respirator devices were used in conjunction with TSI Portacount[®] fit testing. The study involved 700 participants. A mathematical model was developed using the device metrics (pressure, motor speed and power) captured during testing. Device data was segmented into good fit (Fit Factor>1000), marginal fit (Fit Factor 500 –1000) and poor fit (Fit Factor less 500). Device data was captured and transferred via Bluetooth[®] to a mobile handset.

Results: Data analysis demonstrated a correlation to the TSI Portacount[®] fit testing results and indicated protection had a high predictive factor.

Conclusion: This is the first time a methodology has been described for an inbuilt indicator of mask fit run by the wearer in the field. This check could be conducted by the user using a mobile app quickly and inexpensively. Results could be uploaded for remote record keeping by the employer. This methodology would not replace, but would work in conjunction with traditional annual quantitative fit testing. A fast real time check on the job can provide an early warning system for the wearer for poor fitted masks, allowing immediate feedback to adjust and refit the mask-thus reducing the risk of exposure and increasing respiratory safety in the field.

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Figure 1. Figure illustrates breathing pattern captured on the CleanSpace Halo respirator.

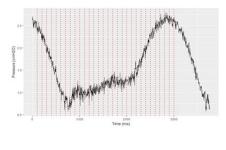
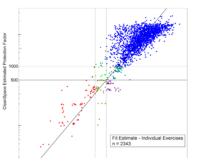


Figure 2. Figure illustrates correlation between TSI <u>Portacount</u>® Fit Testing data (Fit Factor) and CleanSpace Protection Factor



Recent Publications:

- Wilkinson IJ, Pisaniello D, Ahmad J, Edwards S (2010) Evaluation of a large-scale quantitative respirator-Fit Testing program for healthcare workers: survey results. Infect Control Hosp Epidemiol 31(9):918-25.
- Shu-An Lee, Dong-Chir Hwang, He-Yi Li, Chieh-Fu Tsai, Chun-Wan Chen and Jen-Kun Chen (2016) Particle size-selective assessment of protection of European standard FFP respirators and surgical masks against particles-tested with Human Subjects. J Healthc Eng: 8572493.

Notes: