Soft-stretch PPE-Hoods are Replacing Facemasks and Coverall Hoods for More Complete and Comfortable Protection

The Critical Safety Issues with Conventional PPE

The lack of adequate PPE head covering has continuously endangered our emergency responders and healthcare workers during disasters (9/11, Ebola incident, and the recent Covid-19). Many of them suffered severe health issues or got infected by leaving their head and face exposed even though a N95 or surgical mask was worn.



Problem 1: Facemasks are not reliable for respiratory protection due to leakage. Because faces vary in shape and nose-bridge height, there are many gaps between a wearer's face and the edges of a flat facemask. Also, their elastic ear-loops are either too loose or too tight for proper fit. Masks often fall from the nose to cover only wearer's mouth or even hang under the chin protecting nothing. Meanwhile, the elastic straps of the rigid dome-shaped masks have to be uncomfortably tight to seal at all. Even then, the mask moves and leaks when the wearer talks or sweats.



Respirable particles of 1 to 15 µm are considered industrial health

concerns. Generally, smaller particles have higher penetration rate through a filter. However, sub-micron particulates are charged and more easily trapped on mask fibers. Consequently, a surgical mask having PFE of 95% against 1-µm particulates can block 99% of 0.1 µm. While the bacteria and particle filtration efficiency of surgical masks are tested at a flow rate of 28.3 L/min (ASTM F2101 and ASTM F2299), a normal adult's breathing is only about 8 L/min. Higher air flow would create more force to push particles



through the filter. Therefore, any mask capable of blocking 90% of 1- μ m particles in a filtration test should be able to block >90% of a particle mix of 1-15 μ m at normal breathing.

Regarding coronavirus, a nano-sized virus (0.05-0.12 micron) rarely floats in individual form. Even so, a few copies of an airborne virus are unlikely to trigger infection. It requires tens of copies of a virus to swamp a spot on a cell and enable penetration of the membrane and initiation of infection. Airborne transmission of Ebola and Covid-19 from infected

passengers in air travel didn't happen. The facts seem to indicate that the long-distance air transmission rarely carries a critical mass capable of triggering an infection.



To wear a N95 mask is complicated. Required by CDC and OSHA respectively, the wearer has to be pre-qualified by passing a medical evaluation (for chronic respiratory, cardiac, or other medical conditions), fit test (for selecting model, style, and size), and seal test (for airtight fit). Not only do people not always remember which models/makes of N95 masks fit them best, emergency stocks may not always have all models to meet the demands of every individual.

The airtight fit of a N95 mask is created by two strong elastic straps. However, a perfect fit cannot always guarantee against leakage since the mask can move while speaking or sweating. Even worse, the airtight-fit often causes skin pain and bruising in just a short period of time. The discomfort and difficulty in breathing causes wearers to frequently move (pull away) the mask.

Nonetheless, N95 masks have been over-promoted for their usefulness in blocking virus. In fact, the excessive thickness of N95 masks does not provide more benefit than surgical masks in filtering particles when they are used in normal breathing. Instead, it creates great difficulty in breathing. The wearer basically breathes his own exhaled CO₂.

If the risk is low, why go through the hassles required for wearing a N95 mask? On the other hand, in urgent and lethal environments, why risk life on a N95 mask that uses two simple elastic straps and gives an unreliable seal?

The most common threat from many communicable diseases is micron to mm-sized saliva droplets (expelled from talking, coughing, and sneezing) that often carry millions of virus and bacteria. These infectious substances fall on the hair and skin as well as environmental surfaces and allow contact transmission to occur when people touch such contaminants and subsequently touch their nose or mouth. Even though a facemask can block these airborne droplets from short-distance blasts, it only covers half the wearer's face. The best practice in infection-risk environments is to wear a hood covering the entire head, face, and neck all the time.

<u>Problem 2</u>: Adequate protective hoods are missing in conventional PPE. Consequently, workers are left (or elect) to expose their heads and faces in their daily jobs.

<u>Conventional head coverings</u> (such as nonwoven and Tyvek hoods) do not fit properly. Because the materials were stiff, they had to be made baggy to cover different head sizes. Not only did that create too much gapping to provide an effective barrier, they also did not fit well even when incorporated with elastic components.





<u>Coverall hoods</u> are a common alternative. **The disposable coveralls** were developed to shield against contaminants in workplaces. The design has an integrated hood to cover the back of the head and with its elastic edges cover the upper part of forehead. Because wearing a hooded coverall creates severe difficulty in turning the head and bending the neck, it has been prohibited when working in confined spaces or on high structures. Not only does the restricted head movement and mobility quickly tire the wearer, the heat and humidity build up quickly causes anxiety and dizziness. The updated CDC guidance also recommends the use of coveralls without integrated hoods.

Workers' bodies often come in contact with or are held tightly against work objects. To isolate contaminants in liquid or viscous forms, the disposable coveralls need to be made of Tyvek or membrane-laminated or coated nonwoven fabrics to create impermeability. These materials are not breathable and make the wearers hot. On the contrary, healthcare workers' heads and faces rarely ever contact work objects; rather, the heads always stay at a higher position and at a distance. Since heads are more sensitive to heat and humidity, the materials used for making the hoods should have good breathability and require less liquid impermeability (different from that of the body covering).

The Long-Awaited Solution Soft-Stretch Biosafety PPE-Hoods

Made with triple-layers of Latex-free elastic nonwoven fabrics, our Soft-stretch Biosafety Hoods provide effective protection against Covid-19, Ebola, and other communicable diseases by blocking micron-sized particles and fluid and blood splashes.

While disposable PPE apparel is designed for "protecting the wearer", if they are worn by healthcare workers in treating patients they are classified as low-risk medical devices and subjected to FDA regulations

to "protect patients from the wearer". Throughout the development process of our hoods, the FDA guiding principles for surgical masks were followed to design their barrier properties to include <u>breathing resistance (Δ P) of less</u> than 3.5, <u>bacterial filtration efficiency (BFE) of >90%</u>, <u>particle filtration efficiency (PFE) of >95% @ 0.1µ</u>, and <u>level-1 blood penetration resistance</u>.

The Innovative Advantage is "COMFORT":

- <u>Soft Form-fit</u> to securely cover the head without restricting peripheral vision, head movement, and wearer's mobility. When wearing our soft-stretch hoods, the soft form-fit gives the wearer a sense of security from the feel of an isolation layer next to the skin. By covering the entire head, face, and neck, it gives a sense of dignity when the wearer deals with disgusting waste and foul liquids.
- <u>Easy Breathability</u> to keep the head cool for extended wear. It eases the anxiety in stressful work situations.

Solution 1- Replacing facemasks: By wearing properly with goggles that fit the wearer's face (seals around the nose and presses firmly on the nose bridge), our Biosafety hoods can provide effective respiratory protection and replace facemasks in general work environments. Owing to the low air-flow resistance of hood structures and ample space inside the hood, they allow for easy breathability and fast dissipation of exhaled air which reduces goggle fogging.

If high filtration is desired, they can be worn under or over a mask or full-face respirator to provide an additional layer of barrier and a soft cushion of comfort and to reduce gapping from respirator movement due to work or sweat. In the extreme situation, wearing our Biosafety hood under the PAPR or hazmat hood provides continuous protection after removal of the contaminated suit.

Solution 2- Replacing alternative head coverings: It is more practical and economical to wear our Biosafety hood with an un-hooded coverall suit. Wearing two hoods is recommended. That way, the outer layer can be removed upon being contaminated while the inner layer remains in place keeping the wearer protected until there is no longer a danger and the respirator has been removed.



Solution 3- Underlay Protection for PAPR. Powered air purification respirator (PAPR) provides complete coverage for the head. However, of great concern is that the removal of the PAPR hood would immediately expose the wearer's head to contaminants accumulated on the suit. Even changing the doffing procedure to remove the PAPR last leaves a risk of self-contamination from the contaminated PAPR.

<u>Wearing a Biosafety hood under the PAPR or hazmat hood</u> provides continuous protection after removal of the contaminated suit. Our Biosafety hoods should be <u>the first</u> <u>PPE put on and the last removed</u>.

Caution: VitaFlex's soft-stretch hoods are NOT for replacing respirators in OSHA requirements. Not for blocking concentrate detergents, high viscosity solutions, organic solvent, toxic or bio-hazard gases, fumes, or vapors. Not for blocking pressurized liquid and particles.



