# Personal Protective Equipment Protection Against Highly Infectious Diseases

**Abstract**

Blood borne pathogens such as filo virus (Ebola), SARS (Severe Acute Respiratory syndrome), HIV (human immunodeficiency virus), HBV (Hepatitis B*)*, HCV (Hepatitis C*)* can spread through direct contact with infected body fluids or through aerosolized infected particles via mucous membranes (eyes, mouth, nose) or by coming in contact with infected objects such as needles, syringes, shaving blades or from infected surfaces. Hence, use of personal protective equipment is very essential not only for healthcare workers, patients and also for the non-healthcare workers. At the same time, it is equally important for care of surrounding environment. The performance and selection of textile as barrier or as filter against infectious organisms has become very critical depending upon category of biological agent and infection severity. The present article is an attempt to review the information available as of today, related to the Personal Protective Equipment (PPEs) needed for the protection against Ebola. The information is updated on a regular basis by various agencies and industries such as CDC, WHO, OSHA, MSF, ECDC, etc. The final decision on selection of suitable PPE depends upon the available information and has to be taken by safety officers / individuals based on the occupation and the task assigned.

***Keywords: -*** *Ebola, Personal protective textiles, properties*

## Introduction

Ebola comes from filoviridae family of virus called filovirus. Ebola virus is a lipid enveloped filo virus. Usually, they have long filamentous structure sometimes branched or in the shape of '6' or 'u' with length usually between 800-1000nanometer (which can reach up to 14000 nanometers due to concatemerization). It may have diameter of approx. 80 nanometer diameter [1], [2].Ebola virus disease (EVD) was also known as Ebola hemorrhagic fever (EHF) [3].

The primary sources of Ebola virus are believed to be Fruit bats or primates (apes, monkeys).Depending upon risk related to biological contaminants, European directive 2000/54/EEC categorized them into 4 categories, where 1 indicates lowest risk and 4 indicates highest risk. The infection caused by Ebola virus is severe and can often causes fatal illness. Ebola is listed as risk 4 pathogen by WHO considering the high death rate(up to 90%) associated with the disease [4]. Ebola virus can spread from human-animal, human – human contacts. The infection can spread by eating infected food items, by direct contact with infected human or animal body fluids, through blood and other body fluids (breast milk, urine, feces, sweat, tear, semen, amniotic fluid (probable), mucous membrane / respiratory secretions (saliva, vomit, sneeze, cough, spit, vaginal secretions), diahorea, peritoneal fluid, cerebrospinal fluid, synovial fluid, etc [5]. It can spread by punctures (caused by infected needles, blades); sprays (i.e. aerosols, sneeze etc); rashes, abrasions on skin. Ebola viruses can also get entry through mucosal tissues such as eyes, nose, mouth, vagina, etc. Virus may also spread with contaminated surfaces. Ebola virus does not spread through air [3], [6], [7]. Person infected with Ebola virus can show symptoms of infection such as hemorrhagic fever higher than 38.3$^{o}$C, muscle and joint pain, vomiting, diarrhoea, abdominal pain, severe headache, intense weakness and tiredness. It can damage the functionally of liver, kidney and vascular system. The damage to the later system can lead to severe bleeding from organs (external and internal) and under the skin. Death occurs due to low blood pressure and dehydration. Survivors may suffer from joint pains, hearing loss, etc. The Ebola virus disease (EVD) can cause symptoms within 2 to 21 days of infection [1], [3], [7]. Ebola virus infected bodies can remain contagious for up to 60 days [3]. It remains for a long time in semen, breast milks in case of recovery. The virus can survive for several days in liquid or dried material at room temperature [3]. Like EVD, there are other diseases such as Severe Acute Respiratory Syndrome (SARS) is caused by different virus called SARS coronavirus. The coronavirus are RNA viruses with large, enveloped, positive sense single stranded structure. They are classed as one of the largest RNA viruses known to humans with length between 27 to 32kb (29700 nucleotides) and 100-140 nanometer diameters [8]. It is a respiratory disease with initially flue like symptoms, which later on can develop into either direct viral pneumonia or secondary bacterial pneumonia, respiratory failure, liver failure, heat failure, etc [9]. SARS were found in dogs, ferret badgers, palm civets, cats as well as in bats with or without clinical signs. There is no safe cure, vaccines or antibiotics available. The patient must be isolated into a negative pressure room and the healthcare worker must wear full personal protective material as barrier for protection of the full body. Similar to Ebola, SARS spreads through cough, sneeze, talks,

infected droplets, etc. through mucous membranes or by touching infected surfaces, objects etc. The death rate in SARS infected people above the age of 60 years is as high as 50%. In 2003, SARS had crossed boundaries and spread across two dozen countries.
As discussed earlier about EVD and SARS, another virus borne disease is Avian flu. Most avian flu viruses do not infect humans, but few such as H5N1, H7N9 have caused serious infections in humans. Aviation flu is another family of virus, which spreads to humans either by handling dead infected birds (mainly through poultries) or from contact with infected fluids. Symptoms of avian flu can be high fever and influenza like symptoms (cough, sore throat), diarrhoea, vomiting, pain in abdomen and chest, bleeding from nose, gums etc [10].multiple organ dysfunction etc. The name of avian flu includes two protein name letters, where H represents Hemagglutinin protein and N represents Neuraminidase protein.
Considering the severity of above diseases, all the associated professionals such as health care professionals / support staff/ co-workers, mortuary/death workers, emergency responders, patient, doffing donning observers, deployed Ebola responders, waste and water cleaning workers, humanitarian aid workers, college / University workers / researchers, airlines and other travel industry personnel and laboratory workers can be at most risk of coming in contact with infected patient fluids and get infected [11], [12]. Hence, the role of Personal Protective Equipment (PPEs) is very critical for healthcare as well as associated non-health care workers.

**Personal protective garments**
PPEs are used as [13], [14]barrier against infectious contaminated objects

- Effective filter for the infectious contaminated objects
- Barrier to stop cross contamination spread through various infections such as nosocomial infections, human fluid contaminants such as blood, perspiration, saliva, omit, semen, feces, urine and skin cells
  Transmission of microorganisms through PPEs depends upon various factors such as [15].

1. Pore size (filtering capacity) of PPE
2. Thickness of PPE
3. Repellency of PPE
4. Morphology, size, shape and, adaptation of environment
5. Surface tension, volume, viscosity and force
6. Physical, thermal, chemical and environmental stresses
7. Type of carriers (body fluids, sloughed skin cells, lint, dust, respiratory droplets and aerosolized molecules

WHO, CDC and ECDC have listed the number of PPEs and also suggested steps and procedures for donning and doffing of those PPEs in detail. The lists of PPEs specific to occupation and role, task of healthcare or non-healthcare personnel dealing with EVD are suggested in (Appendix 3, 4, 5) .The important [16]–[18]factors to be considered as a guideline in designing PPE are as listed below [13], [14], [19], [20].

- The amount of force by which the contaminated objects can pass through or get filtered (such as in case of sneeze, blood droplets or blood volume with force, vomit particles, coughing, diarrhoea, etc)
- The size of the contaminated objects (i.e. virus, bacteria, fungi, large droplets, aerosols, fluids etc) [21][22].

- Sneeze can generate respiratory infectious particles containing biological organisms in the form of droplet nuclei of 0.5 to 12.0 µm in size
- The sizes of various organisms are as given

Hepatitis B virus- 0.04µ-0.07µ, Filoviruses (Ebola)- 0.08 µ diameter and 0.79-0.97 µm length In general, viruses (0.02 µ to 0.3 µ), bacterial cells and spores (0.3 to 10 µ), fungal spores (2 to 5 µ)

- The type of organs to be protected (eye, nose, mouth, body)
- The exposure time ( Short, medium, long)
- The amount of contaminated objects ( droplet, large volume)
- The mechanical strength ( Puncture resistance, abrasion strength, tensile strength, tear strength, bursting strength)
- End user objective (patient, health care worker, doctors, nurses etc)
- Physical conditions of contaminated object (wet, dry)
- Type of procedure (sterile, non-sterile)
- Severity of disease level (level1, level 2 etc.) or degree of protection required
- Type of surgery (invasive or non-invasive)
- Environmental impact
- weight and surface thickness
- electrostatic properties
- Ease of disposing off, (disposable, non-disposable) or washing requirements

- Cost(related to wash, transportation, energy, people involved for working - manufacturing, disposal etc)
- Waste management
- Some physical characteristics (odor, absorbency, flammability, porosity and linting ability)
- Drapability and feel sensation (eg bare hand and hand with gloves has different sensations)
- Size and skin fitting to end user
- Skin irritation / sensitivity, biocompatibility, comfort factor (breathability, temperature, RH, air circulation)
- Psychological effect for color of PPEs - black color is not acceptable in some community. Moreover, light color is more preferred over dark to easily recognize any dust, dirt contamination, design and shape ( ease of wearing or acceptance of dress code in particular region religion, gender , light reflectance, odour etc)
- Storage, transportation, packaging conditions and liability issues
- Seam, any stich joint, any closures, zips of each PPE must not be an entry point for any contaminated object.
- It is also important that the closures, zip of each PPE must be checked.
- Change in PPE in properties (barrier mechanical etc) after each processes such as wash , sterilization
- The performance of PPE may change/deteriorate with different conditions such as sterilization, washing cycle, storage time and condition, physical/thermal/chemical stresses, so it is advisable to test any PPE after passing through the above conditions. Broadly recommended PPE [5], [23]–[25] for EVD infectious diseases should be considered as guideline only, as there is no well-established list of PPE available. It is getting updated by various agencies from time to time. Various agencies, industries have suggested guidelines for PPEs against EVD. OSHA recommends employers to follow OSHA standards on blood borne pathogens (29 CFR 1910.1030), PPE (89CFR 1910.132), respiratory protection (29 CFR 1910.134). OSHA also published PPE selection matrix for people getting effected due to occupational exposure to EVD [26]. Different agencies classified PPEs as per performance requirement. In general, the recommended PPEs for protection against disease such as EVD are as follows
- Eye and face protection
- Fluid resistant mask or respirator
- Impermeable gloves
- Protective clothing
- Impermeable foot wear

**Eye, face protection / Head covers**

PPE such as goggles, face shield, fluid resistant head cover must cover from hair to head, neck including all mucous membranes (such as eyes, mouth, nose) for the protection against infectious agents. Head covers separate from gown or coveralls are preferred for easy removal [5], [27]. Eye protection is necessary against hazards such as splashes, sprays and respiratory droplets. Face shield with crown and chin protection extended upto ear are recommended [25].The hair, face and neck must be covered with suitable mask / respirator, full face shield helmet or head piece covered with disposable hood, which can cover the neck and extend up to shoulders.

Goggles are recommended over safety glasses for infectious conditions. Indirectly vented or nonvented goggles are preferred over directly vented goggles to protect against splashes, sprays and droplets [25]. Eye and face protection: must have better visibility, fogging and scratch resistance. They must be worn in addition to the respirator / masks. Face shield can provide protection to eyes as well as other areas of faces. Goggles are preferred over safety glasses as the impact protection of safety glass against splashes or droplets is low compared to goggles [25]. Goggles and face shield quality can be as per EU standard directives 86/686/EEC, EN166/2002 or ANSI/ISEA-Z87.1-2010 or equivalent.

Recommended technical specifications / properties for level 1 and level 2 goggles for EVD [5], [27], [28] are given below. Goggles level 1 and level 2 are classified as per guidelines given in [28]:

- Disposable
- Single use
- Latex free
- Good seal with the skin of the face
- Adjustable straps to facilitate good fit
- Flexible frame to easily fit ll face contours without too much pressure
- Covers the eyes and surrounding areas and accommodates for prescription glasses
- Indirect venting to reduce fogging
- No or covered ventilation opening preferred
- Fog and scratch resistant
- Anti-mist spray may be applied prior to donning the goggles
- Goggles are not required if the face shield provides complete coverage of sides and length of the face

- Cover the eyes completely
- Good seal with face skin.
- Provide easy accommodation of any prescription glasses
- Easy to wear and adjust / fit to all face shapes
- Must be too tight or else it might become loose.
- Provide good visibility
- Fog and scratch resistant

Level 1 & level 2 goggles quality can comply withEU standard directive 86/686/EEC, EN 166/2002 or equivalent [28].

Recommended technical specifications / properties for **Face shield** Level 1 & level 2 PPE for EVD. (Face shield level 1 and level 2 are classified as per guidelines given in [28]):

- Disposable
- Single use
- Latex free
- Made of clear plastic
- Provides for good visibility to the wearer and the patient
- Minimizes glare
- Fog resistant
- Adjustable straps/harness to facilitate good fit
- Fog resistant material
- Easy fit and firm fitting of face shield
- Cover whole face length and sides - Complete coverage of sides and length of the face preferable and if this can be achieved, then goggles are not required.

Face shield Level 1 & level 2 PPE quality can comply with [28]

- EU standard directive 86/686/EEC, EN 166/2002 or equivalent
- ANSI / ISEA Z87.1-2010
- Face shield visor with chin guard to confirm to EN166.1.B.3.9

An inner mask may be used to separate the nose and mouth from the eye (visor) area(s) of the full face mask.

Recommended technical specifications for hood level 2 for EVD. Hood level 2 are classified as per guideline given in [28]:

- Disposable
- Single use
- Latex free
- Soft and breathable
- Covers neck and shoulders reaching upper part of gown /coverall
- Facial opening constructed without elastic behavior
- Availability of different sizes
- Preferably fluid resistant
- Preferably sealed /protected seams
- Face Mask / Respirator

Considering the severity of EVD, the mask in isolation area must pass the highest level of filtration efficiency and resistance to fluid penetration [3]. Filters in modern surgical masks and respirators are mainly fibrous in structure and follow mainly three mechanisms to collect particles—initial impaction, interception and diffusion. Sometimes charged fibres are also used to collect particles by electrostatic attraction [29]. The filtering capacity of any respirator or facemask depends upon the number of particles passing through the filter medium or facial leakage [30]. Fluid resistant masks are highly recommended to prevent penetration of splashes, sprays, cough, sneeze, vomit, diarrhoea, virus-contaminated propelled droplets such as saliva or other droplet penetration [3]. Approximately, 40,000 droplets per sneeze and 3000 droplets per a 5 minute talk or cough can be generated [31]. Coughing, sneezing, breathing, speaking may spread droplets loaded with microorganisms of 0.5 µm to 12 µm size in air. Submicrons to 100 µm size particles usually remain airborne. The particle penetration by inhalation can depend on particle size. Particles<100µm (inhalable dust) can enter the nose or mouth through inhalation. Particles up to 10µm or less (thoratic fraction particle) can reach the large bronchioles, lungs. Particles smaller than 5µm (respirable dust) can reach deep inside the lungs lining [25], [32]–[34]. Hence, different types of respiratory protections are recommended based on severity and hazard levels.

Masks are less advised in case of protection against inhalation of small airborne, transmissible infectious agents and contaminants considering the fitting or complete tight sealing problem[35], [36].Respirators with proper filter materials and proper fitting/sealing sizes are preferred more over face masks against small particles such as airborne transmissible infections, contaminant agents.

Almost anyone can use a proper mask without proper training against large droplets of blood/body fluids splashes and sprays contaminated with infectious agents. Proper training is required before the use of the respirators against small particles such as [35], [36] harmful dusts, fogs, smokes, mists, vapors, sprays [23]. Guideline for selection, care, maintenance and use of respiratory equipment are mentioned in EN149:2001, 89/686/EEC directives, EN529 (Europe), OSHA 29CFR 1910.134 (United States of America), AS1715 (Australia and New Zealand) and by OSHA 29 CFR 1910.134 as well as by NIOSH (United States of America) [37].Respirators in USA must perform according to code of federal regulations 42CFR part 84. The N95 type respirators are tested against the worst criteria, using 0.3 µm Sodium Chloride aerosol test with 85litres per minute airflow rate. Surgical masks are classified as category 1 medical device under the medical device directive 93/42/EEC and respirators are classified as category 3 medical devices in Europe. Based on filtering efficiency, the particle filtering face pieces (FFP) are classified in BS EN 149 : 2001 + A1:2009 to FFP1, FFP2, FFP3. FFP3 class mask can protect against pathogens, such as viruses, bacteria and fungus spores. Particulate respirators are recommended against exposure to bio-aerosols, air borne hazardous particles [38]. They can be of different types as mentioned in

Table 1.

1. Filtering half face piece respiratory, where the filter is the entire respiration.
2. Elastomeric (reusable) half mask with a particulate filter
3. Elastomeric (reusable) full face mask with a particulate filter.
4. Powered air purifying respirator (PAPR) that includes a particulate filter.
5. Supplied Air Respirators (SARs) can also be used to improve worker comfort.

If chances of exposure to bio-aerosol are there, it is recommended to use minimum surgical N95 or equivalent level. A full face elastomeric respirator or PAPR has higher APF than a half-mask elastomeric respirator or PAPR. It is also necessary that the respirator / mask must also possess chemical resistance against items such as disinfectants, cleaning agents or moisture sprays. In high risk conditions full face piece (elastomeric) air purifying respirator (APR) with P100 filter or PAPR with P100 filters with full face shield, helmet or hood is recommended. SCBA open circuit self-contained breathing apparatus or any CBRN respirators are also acceptable as alternatives. Any opening, joint must be sealed or taped [18].

**TABLE 1** SOME GENERAL ADVANTAGES AND DISADVANTAGES OF DIFFERENT TYPES OF RESPIRATORS [38].

| **Disposable filtering face piece respirator** | **Reusable half mask or full face piece respirator** | **Powered air purifying (PAPR) respirator** | **Supplied air respirators** |
|---|---|---|---|
| • Disposable, no maintenance<br>• Lightweight<br>• Less expensive<br>• Need separate eye and face protection<br>• Fit testing recommended to ensure respiratory protection | • Often available in multiple sizes<br>• Face pieces can be disinfected and reused<br>• Full face pieces may provide eye and face protection<br>• Fit testing recommended to ensure respiratory protection<br>• Face pieces must be maintained | • Higher level of respiratory protection<br>• Some elements can be disinfected and reused<br>• Less prone to fogging<br>• Improved voice communication and patient rapport<br>• No fit testing required for systems with loose fitting head covers<br>• May not need separate eye and face protection depending on the head covering<br>• Batteries need to be charged and entire unit maintained<br>• Higher initial cost | • Higher levels of respiratory protection<br>• Some systems provide cooled air to the wearer<br>• Can be disinfected and reused<br>• No fit testing required for systems with loose fitting head covers<br>• May not need separate eye and face protection depending on the head covering<br>• Need adequate supply and pressure of compressed breathable air<br>• Unit needs to be maintained<br>• Higher initial cost |

In BS EN143 standard the particulate filters are classified in to three categories P1, P2, P3. According to BS EN 14683 the surgical mask can be classified into Type 1, Type IR, Type II and Type IIR – based on their performance in bacterial filtration efficiency (BFE), Breathability and Splash resistance. IR and IIR are splash resistance type. NIOSH certified respirators are used, when more respiratory protection is required [39]. According to NIOSH non powered particulate (42 CFR part 84) filters can be classified into 9 categories. The N95 respirator for surgical purpose has to pass tests such as fluid resistance, flammability in addition to normal N95 respirator parameters such as face fit test, filter efficiency and breathing resistance tests directed by NIOSH [40]. NIOSH approved filter has minimum 95% filtration efficiency. The filters are identified as N-type, R-type and P-type with filtration efficiencies of 95%, 99% and 99.97% respectively. N 95 means N-type of filter with 95% filter efficiency. All N95 filters are not suitable for prevention against biological agents and biohazard. To achieve this, the filter must be surgical grade. Broadly N, R and P type indicates presence or absence of oil particles.
N-type----Not resistant to oil
R –type – Resistant to oil
P – type – oil proof

**TABLE 2**RECOMMENDED REQUIREMENTS OF SURGICAL GRADE PARTICULATE RESPIRATORS FOR RESPIRATORY SYSTEM PROTECTION AGAINST INFECTIOUS AGENTS

| | |
|---|---|
| Australia / New Zealand- AS1716 | $P_2$ (94%), $P_3$ (99.95%) |
| China | II (95%), I (99%) |
| European Union (perEN143, perEN12941/2, EN149) | CE certified FFP2 (95% or FFP 3 (99.7%) |
| Japan | 2nd Class (95%), 3rd Class (99.9%) |
| Republic of Korea | 1st class (94%), Special (99.95%) |
| USA ( NIOSH 42CFR part 84) | Surgical grade N95 (95%), N99 (99%) and N100 (99.7%) |

Higher filtration efficiency indicates lower filtration leakage [32]. F2100-07 is used for medical mask evaluation. In ASTM F 2100-07, the face masks are classified into low barrier, moderate barrier and high barrier. In ASTM 2100-11 face masks are classified in to level 1, level 2 and level 3 depending on performance against the specified parameters [41]. Surgical face mask shall meet ASTM F2100-11→level 2 or 3(USA) or EN14683 (Europe) type IIR along with EN149:2001[41], [42] or equivalent for EVD. In the case of aerosol generating procedures, lab people handing Ebola specimen, are required to wear FFP2, NIOSH 95, PAPR or equivalent respirators. The mask must also pass the particle filtration test with 0.1µm size particles [3]. Surgical respirators such as FFP2 / N95 or its equivalent with certification from EN149, NIOSH 42 CFR part 84. AS1716 are recommended for minimum safety level [43], [44]. In Europe perEN143, aP2 or P3 filters or PAPR system (perEN12941/2 with TH2 or TH3 rated head top system and face mask with TM2 or TM3 particulate holding ratings are recommended [43]. while in Australia and New Zealand (per AS 1716), P2 or P3 fitter are recommended [41]. NIOSH approved PAPR with self-contained filler and blower unit, integrated inside the helmet with a full face shield, helmet or headpiece is preferred [5], [45]. N95 respirator with single use (disposable) full face shield and surgical hood up to shoulders is recommended. Recommended surgical grade particulate respirators for respiratory system protection against infectious agents are given in

Table 2[41], [43], [44], [46]. The test must be performed by giving any pretreatment considering a physical, chemical, thermal stresses and changes in performance of mask due to various processes such as sterilization, laundering, perspiration, etc. Masks in isolation areas must pass ASTM F2100 level 3, which means highest filtration efficiency and resistance to fluid penetration. A Mask also must pass the particulate filtration test even with 0.3microns. Particulate filtration efficiency (PFE %) results of any surgical mask is not comparable to NIOSH filtration testing, i.e. "The filter media of a surgical mask with a very high PFF ( >95%) may be less than 70% efficient when tested with the NIOSH N95 lest method"[47].

Considering the life threatening nature of EVD, the recommended quality of respirators / masks are EN14683 type IIR, ASTM F2100 level 3 or equivalent. CDC also recommended NIOSH – approved powered air purified respirators for EVD [11]. Details pertaining to ASTM F2100 are given in

Table 3.
Bacterial filtration efficiency (BFE) is calculated in percentage using biological aerosolized staphylococcus Aureus in 6-stage cascade impactor. Particle filtration efficiency test [48] is done by counting upstream (feed) and downstream (filtered) mono-dispersed aerosolized particle flow through the face mask material using light scattering particle counting (size range 1.0 to 5.0µm) principle.
Fluid resistance test [49] is performed using visual detection of synthetic blood penetration in close proximity (within 300mm), at different high velocity into face mask material to check a pass / fail; where fail indicates penetration of fluid on inner facing side (i.e. side contacting wearer's side). Similar to ASTM 1862 test method, ISO 22609 also tests resistance of mask against synthetic blood penetration (fixed volume, horizontally projected. The impact velocity of blood depends on face masks upon patient blood pressure, puncture distance from mask size of the puncture. In ISO 22609, a fixed volume of blood with defined distance to impact, orifice size and fluid velocity is sprayed horizontally on the mask to visually check any evidence of blood penetration on inner side of face mask. The results are again indicated as pass or fail, same as in ASTM 1862.

**TABLE 3**ASTM F2100[50]

| Test parameters | Description | Test matter |
|---|---|---|
| Bacterial filtration efficiency (BFE %) | Resistance of bacterial entry through mask. Higher BFE%-→ more resistance to bacterial entry using a biological aerosol of staphylococcus aureous | ASTM F2101 can measure up to 99.9%(ASTMF2101-07) |
| Particulate efficiency filtration (PEF %) | Resistance of particles entry through mask. Higher PFE%--→more resistant to particulate entry at 0.01 micron | ASTM F2299 |
| Fluid resistance / Splash resistance pressure (Pass or fail) | Resistance to splash and spray through mask using synthetic blood at different velocities /pressures .Higher fluid resistance values indicates mask resistance | ASTM F1862 |
| Delta P/ Differential pressure | Breathability/comfort, Lower delta P, higher breathability | MIL-M-36954C |
| Flammability | Flame spread | 16 CFR part 1610 |

The resistance of air flow / breathing resistance is determined by MIL-M-36954C i.e. by passing the controlled flow of air through the sample and then measuring the pressure difference across the same (i.e. before and after the sample).
List of important properties to be considered for respiratory protection devices for EVD [42], [50]–[53] are given below

- Disposable
- Single use Fluid resistant 160mm Hg
- Latex free
- Easy to differentiate between internal and external surfaces
- Respirators must also be tested against fitting on the face and face seal in dry as well as moist conditions, while talking, motion or head movement, routine activities.
- Good breathability→The mask must be breathable and it must not collapse with desired fluid resistance
- Desired Filtration Efficiency. A higher face mask filtration efficiency means more close structure and hence reduced breathability and comfort.
- Stable in wet / dry conditions or against body fluids : saliva, perspiration, nasal excretions
- Desired Filtration Capacity
- Desired Filtration moisture absorption from exhaled air
- Low Clogging
- The face mask material degradation rate in specific environment (including body fluid, sneeze, talk, respiration etc) and duration of face mask.
- Damage free product and its parts (such as strap, Inhalation valve, exhalation valve).

- Desired mechanical performance / failure of materials and parts such as exhalation and inhalation valves, straps.
- Able to withstand cleaning / disinfection chemicals and its procedure without damage / reduced performance for reusable products.
- No release of harmful substances from the material of respiratory protective device
- The contact surface of mask must be free of sharp edges and burrs.
- No skin irritation or any adverse effect of face mask to the wearer.
- CPSC recommended 16 CFR part 1610 standard to discourage usage of flammable clothing, textiles.
- Head harness design should allow easy doffing / donning process.
- Optimum harness adjusters, harness strength and ability to hold mask securely and leakage proof, harness-head comfort, security of fastening etc.
- The components of the filters (valves, harness attachment points etc.) should be tested for penetration using different type of aerosols according to EN 13274-7
- Secure connection of demountable part connections and security
- Field of vision must not be compromised in the design of respiratory device
- The mask design in terms of close fit is also important. It is also a mentioned parameter in BS EN 14683:2005 such as differential pressure may not be suitable for respiratory protective device. Hence, such device should fulfill relevant standards.
- Recommended technical specifications for FFP 3 respiratory mask level 2 (FFP3 level 2 is classified as per guideline given in [42])for EVD is as follows
- Shape that will not collapse easily
- Latex free
- Adjustable straps to facilitate good fit
- High filtration efficiency –filter performance ≥99%
- Total inward leakage(max) <2%
- Fluid resistant
- Good breathability
- Non-irritating
- Non-valved or shrouded expiration valve, where both mask and valve are fluid resistant (i.e. valve is shrouded/covered by fluid resistant material)

**Gloves**

Impermeable double gloving can prevent exposure to contaminated fluids due to punctures, tears or any needle/sharp object related injuries. Outer glove with long cuff ideally up to mid forearm is preferred. Inner glove worn under the cuff of gowns / coveralls provides better security against chances of wrist area contaminations [54]. Gloves can be sealed by a tape with the gown. Nitrile gloves are generally preferred over latex gloves because of their higher chemical resistance.

Water proof disposable gloves or cover all with thumb, finger loop to anchor sleeves and covered with apron are recommended. The gloves must be secured (topping, thumb hook,etc) over the gown sleeves to stop the penetration of infection contaminants.

**Surgical gloves are used as protective device to**

- reduce risk of cross contamination,
- reduce hazard associated with harmful chemicals/substances such as strong antiseptic agents
- prevent any sharp object cut or puncture such as needle or blade[31].

Usually, gloves consist of two types of materials: glove body material and glove lubricating material. Glove body material plays a very important role i.e. latex glove are more flexible with dexterity and tactility and can reseal in case of puncture compared to synthetic rubber gloves.

The glove lubricating material can be powder or liquid (powder free). The lubrication material acts as lubricant, during donning and doffing process. It stops sticking of gloves during long term storage [31]. Powder free gloves are more preferred as virus can contaminate and spread through the powder. In the case of powdered gloves the gloves can be treated with antimicrobial powder coating.

The glove can be punctured due to natural wear and tear, long exposure to deteriorating chemicals, incision of sharp objects (needle, knife, bone fragments etc) during operations [31].In the case of highly infectious microorganisms, multi-layer gloving can be a solution as the puncture rate of inner gloves was found to be only 2% in the case of double gloving [42][29][30], but at reduced dexterity and tactile sensation [31].

**The ideal gloves can have below parameters [42], [54]**

- Low hypersensitivity of materials with daily medical practice

- Puncture resistance and tear resistant
- Chemically resistant to exposure with disinfectants and antimicrobial agents
- Ease of donning/doffing
- Non-allergic, non-toxic powder/powder free coating with desired properties such as antimicrobials
- Tactility
- Dexterity
- Recommended technical specifications for inner and outer gloves are listed below for EVD [42]
- Nitrile, Latex free
- Non-sterile
- Single use
- Disposable
- Extended cuff
- Beaded cuff
- Ambidextrous
- Powder free
- Intermediate length (for inner gloves approximately 12 inches and for outer gloves approximately 16 inches)
- Different sizes-small, medium, large, extra-large
- Darker colour to differentiate from outer gloves in level 2 PPE – Inner gloves and Lighter colour to differentiate from inner gloves in level 2 PPE – Outer gloves
- Textured fingertips
- Inner and outer gloves quality can comply with [42]:
- EU standard directive 93/42/EEC Class 1, EN 455
- EU Standard directive 89/686/EEC category III, EN 374
- ANSI / ISEA 105 – 2011
- ASTM D 6319-10 or equivalent

**Gowns / Coveralls / Aprons**

Classification of PPEs based on occupation, task and conditions is given by 3M [46]. The surgical gown and drape performance requirement are classified into two main groups as ‘standard performance’ and ‘high performance’ with two sub-categories under both as ‘critical product area’ and ‘less critical product area’. Clean air suit is not a substitute for surgical gown but it is an addition to surgical gown.

The fluid resistant gowns, coveralls and aprons can be selected by keeping the following facts in mind:

- Material thickness
- Fluid resistance
- Seam integrity
- Amount of time a worker can stay in comfortable condition.

The recommended protective clothing for EVD can be single use fluid resistant/impermeable gown extending up to mid-calf or cover all without integrated hood and with or without integrated socks are acceptable. Higher breathability, low heat stress, familiarity of health workers, availability, etc., makes gown as more preferred option [11,64]. Disposable fluid resistant / impermeable apron cover provides protection against patient vomits and diarrhoea, blood, body fluid or other excrement. The apron must be impermeable by coating it with a fluid impermeable material such as PVC or rubber. Ideally, a gown and apron or coverall and apron combination is preferred, where gown or coverall fabric must have resistance to blood / body fluid or blood – borne pathogen penetration .An apron can be easily replaced compared to gown/cover all, so it must be worn on top [23]. The gown/ coverall must be tested against blood, body fluid, blood borne pathogen penetration [26]. European Union’s directive suggests that an employer must provide suitable clothing to workers in case of biological hazards (2000/54/EC).The recommended quality for EVD disposable gown are either high performance level fluid penetration resistance of EN13795, AAMI level 3 performance level or AAMI PB70 level 4 performance against blood borne pathogen penetration. To claim an AAMI 4 pass AQL 4.0% - only 3 out of 32 times can fail. Coverall quality are required to be resistant to blood and any body fluid penetration – exceeding theISO 16603 class 3 or equivalent resistance to blood borne pathogen penetration – exceeding ISO 16604 Class 2.Barrier property of a gown increases as the level number increases from 1to4. Level 4 gowns also have to pass acceptable quality level (AQL) 4.0.

**Table 4** indicates the recommended standards to be met for EVD [26], [42]:

**Table 4** Recommended level of protection for PPEs

| | | |
|---|---|---|
| Low risk of exposure to blood and body fluids | Fluid resistant Gown | Minimum required level →ANSI / AAMI PB70 LEVEL 3 |
| | Fluid resistant coveralls with seams | 42 Impact penetration test at 1 gram or below and AATCC 127 hydrostatic head test at 50cm or above.<br>OR<br>EN 20811 hydrostatic head test at 50cm and above<br>OR<br>ASTM F1670, synthetic blood penetration test<br>OR<br>ISO 16603 synthetic blood penetration test at 3.5 kPa or above.<br>EN13795 high performance level |
| High risk of exposure to blood and body fluid | Impermeable Isolation or surgical gown with seam. Tested for resistance to blood borne pathogen penetration.<br><br>Impermeable coveralls with seam | ANSI / AAMI PB70 LEVEL 4<br>ASTM F 1671 – Blood borne pathogen penetration resistance.<br>ISO 16604 – Blood borne pathogen penetration resistance at 14 kPa or higher |
| | Seam | Appropriate sealing by seam (eg: taped seal) |

PPEs must act as a barrier according to EN14126:2006 criteria and test method. EN14126:2006 – can be considered as a guideline for EVD until more specific guidelines are established. EN14126 explains the series of tests and the minimum quality requirements of PPE against infective agents[24]. EN14126 includes all tests ISO 16603, ISO 16604, ENISO 22610, ISO 22611, ISO/DIS 22612 for PPE garments.

- Resistance to synthetic blood penetration ISO 16603:2004
- Resistance to Blood borne pathogen penetration ISO 16604:2004
- Resistance to biologically contaminated solid particle penetration ENISO 22612:2005
- Resistance to biologically contaminated liquid aerosol penetration ISO/DIS 22611:2003
- Resistance to wet bacteria penetration ENISO 22610:2006

BSEN 14126:2003 indicates requirement of PPE material testing against 4 methods. The PPE are classified in to different classes according to the test methods ISO / FDIS 16604, ISO 22610, ISO / DIS 22611, ISO 22612 (

Table 5). The seam joints and assemblages requirements against infective agents are according to prEN14325 [7]. Then the requirement for the whole suit against infective agents shall fulfil relevant EN340 requirements. The suit should be flexible, comfortable, with minimum hindrance to movements with required protection.
As mentioned in EN14126 a fabric can be classified into number of classes as given in

| Standard | Unit of standard | Description | Classes |
|---|---|---|---|
| ISO / FDIS 16604 | Hydrostatic pressure (kPa) | Resistance to contaminated liquid penetration under exposure to hydrostatic pressure | 6 classes according to performance |
| ISO 22610 | Breakthrough time (t Min.) | Resistance to infective agent penetration due to mechanical contact with substances containing contaminated liquids | 6 classes according to performance |
| ISO / DIS 22611 | Penetration ratio (log) | Resistance to contaminated liquid aerosols penetration | 3 classes according to performance |
| ISO 22612 | Penetration ratio (log cfu) | Resistance to penetration by contaminated solid particles | 3 classes according to performance |

Table 6. For bio hazardous condition, they must fall under CE certified category III. Broadly protective clothing for infective agents are classified into - Type 1a,1b,1c,2 according to EN943-1, EN943-2; Type 3 according to EN466, Type 4 according to EN465, Type 5 According to prEN ISO 13982-1, Type 6 according to PrEN13034 and partial body protection according to EN467.

**TABLE 5** CLASSIFICATION OF PPE MATERIAL REQUIREMENTS ACCORDING TO EN14126

| Standard | Unit of standard | Description | Classes |
|---|---|---|---|
| ISO / FDIS 16604 | Hydrostatic pressure (kPa) | Resistance to contaminated liquid penetration under exposure to hydrostatic pressure | 6 classes according to performance |
| ISO 22610 | Breakthrough time (t Min.) | Resistance to infective agent penetration due to mechanical contact with substances containing contaminated liquids | 6 classes according to performance |
| ISO / DIS 22611 | Penetration ratio (log) | Resistance to contaminated liquid aerosols penetration | 3 classes according to performance |
| ISO 22612 | Penetration ratio (log cfu) | Resistance to penetration by contaminated solid particles | 3 classes according to performance |

**TABLE 6** PROTECTIVE CLOTHING TYPE ACCORDING TO 14126

| Type | Relevant standard | Description |
|---|---|---|
| 1a,1b,1c,2 | EN943-1<br>EN943-2 for ET suit | |
| 3 | EN466 | Protection against liquid chemicals (liquid for tight clothing connection) |
| 4 | EN465 | Protection against liquid chemicals (spray for tight clothing connection) |
| 5 | prENISO 13982-1 | Protective clothing for use against solid particulate chemicals – Part 1:performance requirements against airborne solid particles |
| 6 | prEN13034 | Protective clothing for use against liquid chemicals |
| Partial body protection | EN467 | Protection against liquid chemicals (garment protection) |

The above types are for resistance against chemical protection. But for showing protection against infective agents suffix “B’ is mentioned eg. Instead of Type 3, it will be written as type 3B.

ISO 16603: The surface tension values of body fluid / blood are in the range of 0.04 to 0.060N/m (excluding saliva). Even though, properties such as surface tension, viscosity, red colour are representatives of blood and some of the body fluids. Not all the properties of synthetic blood have properties matching with real blood such as polarity (wettability), coagulation property as well as the cellular (biological) content of blood [39]. According to ISO 16603, the synthetic blood is prepared using carboxymethle cellulose, distilled or deionized water, amaranth dye and other ingredients to prepare a solution with 0.042 ± 0.002 N/m surface tension, 7.3±1 pH, 2.7±0.3 mPa.s viscosity and 12.0±1.2 mS/cm. The seam barrier or any closures need to show the same standard and effective barrier performance as that of the PPE material. For disposable cover, all recommended quality compliance are ISO 16603 class 3 level pressure exposure against blood and body fluid penetration or ISO 16604 class 2 exposure pressure against blood borne pathogen penetration [13]. ISO 16603:2004 indicates 4 test procedures for synthetic blood (surface tension 0.042 +/-0.002 N/m, pH 7.3+/-0.1, viscosity 2.7 +/-0.3 mPa.S, conductivity 2.0+/-1.2mS/cm) penetration with different time and pressure protocols. The specimen with normal outside of fabric facing toward the synthetic blood reservoir is placed in the penetration cell. The test liquid with defined pressure and time is applied to the specimen. The pressure is changed from 0 kPa to 1.75 kPa, 3.5 kPa, 7kPa, 14kPa and finally to 20 kPa. The pressure is changed at the rate of 3.5 ± 0.5 kPa /s. In the event of occurrence of synthetic blood or any wetness, the test is stopped. The test and the time and pressure at the time of failure is recorded. If no penetration occurs at the described pressure and time, the specimen passes the test.
ISO 16604 can be performed at visual end-point in ISO 16603, which is the highest pressure with no visible penetration. Positive results of ISO 16603 are desired to perform as per ISO 16604. ISO 16604 is hydrostatic pressure test, which describes the method to know the resistance of fabric to surrogate virus (phi-X174 bacteriophage) using ISO 13994 test apparatus. The phi-x174 bacteriophage suspension surface tension is adjusted to synthetic blood / body fluid stimulant (0.042 ± 0.002) N/m. Phi-x 174 is one of the smallest known viruses (0.027µm dia.) smaller size, spherical (icosahedral) shape / morphology, environmental stability, non-human infectivity, have no envelope, high assay sensitivity, rapid assay and high titre makes phi-X174 as favorable bacteriophage for this test.
The specimen is exposed to virus containing nutrient broth at specified time and pressure sequence in ISO 133994 instrument. Virus penetration is determined using assay procedure (even in case of liquid penetration is not visible). The results are quoted in terms of Pass / Fail.

According to ANSI/AAMI PB 70:2012 (

Table 7), the protective garment / fabric can be classified into 4 levels,. Where level 4 shows most protective performance. The classification is decided based on liquid barrier performance against the below standard methods.

**TABLE 7**CLASSIFICATION ACCORDING TO ANSI / AAMI PB70 : 2012

| Method No | Detail of the method |
|---|---|
| AATCC 42 | Resistance of fabric to water spray impact (Water Resistance Impact penetration Test) |
| AATCC 127 | Resistance of fabric to water penetration under hydrostatic pressure (Water Resistance : Hydrostatic Pressure Test) |
| ASTM F 1670 | Resistance of material to synthetic blood penetration |

| | |
|---|---|
| ASTM F 1671 | Resistance of materials to blood-borne pathogens penetration |

AATCC 42can be used to measure the fabric characteristics of wetting or penetration of water. The fabric and blotter paper with defined dimensions are placed on an inclined stand. The blotter paper is placed underneath the fabric after weighing (dry weight) at 0.1 gram precision. A defined volume of distilled, de-ionized or reverse osmotic water is sprayed on the fabric through a funnel without imparting any swirling motion of the water in the funnel. After spraying, the weight of blotter is again taken at 0.1 gram precision. The increase in the weight of blotter is taken as the result.
As per AATCC 127, the resistance of fabric under hydrostatic pressure is tested. The surface of fabric to be tested is clamped facing the water side. The water is forced at a pressure gradient of 60mbar/min. towards the specimen. The hydrostatic pressure at which 3 water droplets penetrate / appear is measured.
Depending on the task, occupation and role, the type of suit according to ISO16602:2007 can be selected from type 3 (multi layered laminates), type 4 (non breathable laminates, type 5/6 (microporous laminates or SMMMS/microporous laminate hybrid). Following physical test parameters are mentioned for protective clothing against EVD according to EN14325 [38].

- Abrasion resistance method 2 EN530:1994
- Flex cracking resistance, method B ISO7854
- Trapezoidal tear resistance ENISO 9073-4:1997
- Tensile strength: ENISO13934-1:1999
- Puncture resistance: EN 863:1996
- Seam strength ENISO 13935-2:1999

Liquid chemical permeation test against $H_2SO_4$ (EN 374:2003)and NaOH (EN374:2007) are also recommended. ASTM F1670-07is a visual method to detect the resistance of the personal protective structure and its material using body fluid simulant (synthetic blood), which is similar to ISO 16603 with few changes. The simulant blood is prepared to simulate certain properties of blood ((and some body fluids) such as viscosity, surface tension (usually 0.042 to 0.060 N/m) and colour under continuous liquid contact for a specific time and pressure. The results can be pass or fail, where fail means the synthetic blood can penetrate the structure/material. ASTM F1670 results can only show resistance of PPE against synthetic blood, but results cannot be used to detect resistance to viral penetration. ASTM F 1670 and F1671 are the North American standards for blood borne pathogens.
ASTM F 1671 is standard test method to measure PPE garment material resistance against blood-borne pathogen penetration using Phi-X174 Bacteriophage, which is similar to ISO 16604 with few changes. It is also essential PPE garment seams must pass above test [55].The positive result in ASTM F1670 can be considered to encourage the further subsequent barrier property testing of material using ASTM F1671 method.
In order to detect pass/fail test for a viral penetration; ASTMF1671 is recommended. ASTM F1671 method results ( by visual viral detection) can be used to test the resistance of personal protective structure/material against surrogate microbes; usually Phi-X174 bacteriophage in continuous liquid contact conditions. In order to visually detect viral penetration the biologically based assay is used. Phi-X174 simulates pathogenic virus such as HCV and it is not pathogenic to human.
As mentioned earlier, the requirement for PPE in EVD varies as per task, role and occupation. ASTM: F2407-06 standard for surgical gown describes different parameters to be considered for surgical gown depending on endues/requirement (

Table 8).
ASTM F 2407 guideline for surgical gown AAMI level 3 method same properties – tensile, tear,
ASTM F 2407-06 also suggests to test the gown parameters (

Table 8)
BSEN 13795:2011 (

| Test parameter | Test method | Unit | Remark |
|---|---|---|---|
| Tear strength | ASTM D 5587 option 1 for woven fabrics<br>ASTM D 5733 for non woven fabrics | Pounds force (lbf) or Newton (N) | Combination of all material layer used in gown shall be tested<br>Higher value indicates higher strength |
| Tensile strength | ASTM D 5034 | Pounds force (lbf) or Newton (N) | Combination of all material layers used in gown shall be tested |

| | | | |
|---|---|---|---|
| | | | Higher value indicates higher strength |
| Seam strength | ASTM D 1683 for woven fabrics<br>ASTM D 751 for stretch woven & knit | Pounds force (lbf) or Newton | Combination of all material layer used in gown shall be tested<br>Higher value indicates higher strength |
| Linting | ISO 9073 part 10 | Number of particles | Each side of the fabric for each type of material used in gown |
| Evaporation resistance | ASTM D 1868 part B | Pascal meters squared per watt (Pa $m^2$/W) | Measures material comfort<br>Lower evaporation resistance means higher amount of water vapour will go through the material |
| Water vapour transmission resistance | ASTM D 6701 (Nonwoven and plastic barrier material) | Grams of water vapor per square meter of fabrics per day (g/$m^2$/day) | Measures material comfort<br>Higher water vapor transmission rates means higher water vapor transfer through the material |

By membranes of a surgical team to prevent transfer of ineffective agent " – BSEN 13795:2011 surgical drape : drape covering the patient or equipment to present transfer or ineffective agent –BSEN13795:2011. The test methods specified in BS EN 13795: 2011 is common for surgical gown and surgical drape, but it indicates different requirements to be met. The surgical gown and drape performance requirements are classified into many groups as standard performance and high performance with two sub-categories under both as critical product area and lears critical product area". Critical zones (s) are the areas of gown where direct contact with blood and body happens the test methods specified in BS EN13795: 2011 is common for surgical gown and surgical drapes, but it indicates different requirements to be met.
Recommended technical specifications for long sleeved gowns suitable for only level 1 and suitable for both level 1 and level 2 for EVD [42]

- Disposable
- Single use
- Latex free
- Fluid resistance
- For level 1 →Provides full impervious cover and for both level 1 and level 2 → Provides full impervious cover (360 degree)
- Cuffs(preferentially water proof)
- Different sizes available
- for level 1 → Different length available-chosen length should reach to wearer's mid calf and for both level 1 and level 2 → Different length available-chosen length should reach to wearer's mid calf and cover top of knee high rubber boots
- Light colours preferable to better detect possible contamination
- Fasteners /ties at neck and waist
- Preferably secured with velcro at neck for easy doffing

Table 9) also summarised the test and performance requirements to be met by surgical gowns / drapes and clean air suits. BSEN 13795 :2011 also summarized the test and performance requirements to be met by surgical gowns / clarity air suits surgical gown work

**TABLE 8** PHYSICAL PROPERTIES REQUIRED

| Test parameter | Test method | Unit | Remark |
|---|---|---|---|
| Tear strength | ASTM D 5587 option 1 for woven fabrics | Pounds force (lbf) or Newton (N) | Combination of all material layer used in gown shall be tested<br>Higher value indicates higher strength |

| | | | |
|---|---|---|---|
| | ASTM D 5733 for non woven fabrics | | |
| Tensile strength | ASTM D 5034 | Pounds force (lbf) or Newton (N) | Combination of all material layers used in gown shall be tested<br>Higher value indicates higher strength |
| Seam strength | ASTM D 1683 for woven fabrics<br>ASTM D 751 for stretch woven & knit | Pounds force (lbf) or Newton | Combination of all material layer used in gown shall be tested<br>Higher value indicates higher strength |
| Linting | ISO 9073 part 10 | Number of particles | Each side of the fabric for each type of material used in gown |
| Evaporation resistance | ASTM D 1868 part B | Pascal meters squared per watt (Pa $m^2$/W) | Measures material comfort<br>Lower evaporation resistance means higher amount of water vapour will go through the material |
| Water vapour transmission resistance | ASTM D 6701 (Nonwoven and plastic barrier material) | Grams of water vapor per square meter of fabrics per day (g/$m^2$/day) | Measures material comfort<br>Higher water vapor transmission rates means higher water vapor transfer through the material |

By membranes of a surgical team to prevent transfer of ineffective agent " – BSEN 13795:2011 surgical drape : drape covering the patient or equipment to present transfer or ineffective agent –BSEN13795:2011. The test methods specified in BS EN 13795: 2011 is common for surgical gown and surgical drape, but it indicates different requirements to be met. The surgical gown and drape performance requirements are classified into many groups as standard performance and high performance with two sub-categories under both as critical product area and lears critical product area". Critical zones (s) are the areas of gown where direct contact with blood and body happens the test methods specified in BS EN13795: 2011 is common for surgical gown and surgical drapes, but it indicates different requirements to be met.
Recommended technical specifications for long sleeved gowns suitable for only level 1 and suitable for both level 1 and level 2 for EVD [42]

- Disposable
- Single use
- Latex free
- Fluid resistance
- For level 1 →Provides full impervious cover and for both level 1 and level 2 → Provides full impervious cover (360 degree)
- Cuffs(preferentially water proof)
- Different sizes available
- for level 1 → Different length available-chosen length should reach to wearer's mid calf and for both level 1 and level 2 → Different length available-chosen length should reach to wearer's mid calf and cover top of knee high rubber boots
- Light colours preferable to better detect possible contamination
- Fasteners /ties at neck and waist
- Preferably secured with velcro at neck for easy doffing

**TABLE 9** PERFORMANCE REQUIREMENTS FOR SURGICAL GOWNS

| Test parameters | Method | Unit | Remark | |
|---|---|---|---|---|
| Resistance to microbial penetration (Dry) | ENISO 22612 | CFU (colony forming unit) | | D,G,S |

| | | | | |
|---|---|---|---|---|
| Resistance to microbial penetration (wet) | ENISO 22610 | $I_B$ | Iβ= 6; is the maximum level means no penetration. | D,G |
| Cleanliness-microbial | ENISO 11737-1 | CFU/100cm$^2$ | "Freedom from population of viable micro-organisms on a product and / or a package " | D,G,S |
| Cleanliness-particulate matter | ENISO 9073-10 | IPM=$\log_{10}$ of particulate matter Index for particular matter | "Freedom from particles that are contaminating a material and can be selected but are not generated by a mechanical impact". | D,G,S |
| Linting | ENISO 9073-10 | $\log_{10}$ of the lint count value -the coefficient of linting | "Release of fibre fragments and other particles during handling and use" | D,G,S |
| Resistance to liquid penetration | EN 20811 | Cm $H_2O$ | The outer side of the product is exposed to the test liquid with specified rate of pressure. | D,G |
| Bursting strength (Dry) | ENISO 13938-1 | kPa | Test both sides | D,G,S |
| Bursting strength (Wet) | ENISO 13938-1 | kPa | Test both the sides of the wet sample preparation according to EN29073-3 | |
| Tensile strength (DRY) | EN 29073-3 | N | Both in level & longitudinal direction of fabrics | D,G,S |
| Tensile strength (Wet) | EN 29073-3 | N | Both in level & longitudinal direction of fabrics | D,G |
| D = Drape, G = Gown, S = Clean air suits | | | | |

Recommended technical specifications for cover all level 2 for EVD [42]

- Disposable
- Single use
- Latex free
- Fluid resistant
- Sealed /protected seams
- Zipper covered by adhesive flaps
- Large ring pull zipper preferable for easy doffing
- Thumb/finger loops to anchor sleeves in place
- Different sizes available
- Light colours preferable to detect possible contamination
- Elastic wrists
- Non-elasticated ankles preferably for easy doffing over rubber boots
- Coverall level 2 quality can comply with
- Resistant to blood and body fluid penetration → at least ISO 16603 class 3 exposure pressure or equivalent OR
- Resistance to blood borne pathogen penetration → at least ISO 16604 class 2 exposure pressure or equivalent OR
- Compliant with EN 14126 or equivalent OR
- Compliant with ASTM F 1670 and ASTM F 1671 or equivalent

Recommended technical specifications for Apron level 2 PPE for EVD [42]

- Disposable
- Single use
- Latex free
- Fluid resistant
- Made of polyester with PVC coating , or other water proof material straight with bib

- Minimum basic weight : 250g/m$^2$ or 60 microns +/- 10%
- Covering size : approximately 70-90 cm width x 120-150cm height , or standard adult size
- Neck strap allows for tear off with waist ties.

**Foot wears**

Footwear: Water proof / fluid resistant, non-slip, completely sealed boots up to knee high are recommended. Fluid resistant boot can be cleaned easily. Shoe / boot must allow easy movement. The disposable water impermeable shoe cover extending upto mid-calf is recommended. Disposable, single use fluid-resistant, impermeable and puncture resistant shoe covers upto at least mid-calf, with ease of movements, non-slippery material are also recommended. Boot with improved comfort and fewer traumas to feet are preferred. Shoe without laces are preferred.

The opening between footwear and garment must be sealed or tapped in such a manner that the wearer's movements are not restricted. At the same time there must not be any strain on garment [18].

Recommended technical specifications for boots level 2 for EVD [42]

- Generally single use for EVD level 2 PPE
- Latex free (preferable)
- Fluid resistant
- Knee high , in order to be higher than the bottom edge of the gown
- Different sizes available
- Nonslip and have a pvc sole that is completely sealed
- Light color preferable to detect possible contamination
- Heel
- Lip for ease of doffing

**TABLE 10** TYPE OF CHEMICAL PROTECTIVE CLOTHING ACCORDING TO ISO 16602:2009

| Description | Type | Example of Type of Suit |
|---|---|---|
| **Gas Tight** *(They shall cover the whole body, including hands, feet and head)* | 1 A | Chemical protective suit with self-contained breathing apparatus worn inside the suit |
| | 1 B | Chemical protective suit with self-contained breathing apparatus worn outside the suit |
| | 1 C | A gas tight airline chemical protective suit fitted with external source of breathable air providing positive pressure inside the suit |
| **Non Gas Tight** | 2 | An Airline suit (external source of air) which is not gas tight |
| **Liquid Tight** *(Full body chemical protection with liquid tight connections between parts of clothing)* | 3 | One piece coverall, or two piece suit, with or without hood or visors, with or without boot-socks |
| **Spray Tight** *(Full body chemical protection with spray tight connections between clothing)* | 4 | One piece coverall, or two piece suit, with or without hoods or visors, with or without boot-socks |
| **Air-borne Solid Chemical Resistant** *(Full body chemical protective clothing against air borne solid chemicals)* | 5 | One piece coverall, or two piece suit, with or without hoods or visors, with or without boot-socks Shall meet ISO 1982-1 requirements |
| **Limited Protective Performance against liquid chemicals** *(Full body chemical protective clothing against air borne solid chemicals)* | 6 | One piece coverall, or two piece suit, with or without hoods or visors, with or without boot-socks Shall meet ISO 1982-1 requirements |
| **Partial Body Chemical Protective Clothing (PB)** | PB as Prefix | Aprons, boot / shoe covers, gowns, hoods, jackets, lab coats, sleeve protectors (covering only part of body – type 3, 4 or 6 can be designated as PB clothing and written as PB (3), PB(4), PB(6) |

**TABLE 11** SEAM REQUIREMENTS

| Integrity of whole chemical Protective clothing material | Chemical resistance of Protective clothing material |
|---|---|

**TABLE 12** PERFORMANCE RELATED REQUIREMENT

| Testing requirement | Standard to follow |
|---|---|

| | |
|---|---|
| • Leak Tightness<br>• Inward Leakage<br>• Liquid (Jet test) Penetration resistance<br>• Liquid (Spray test) penetration resistance<br>• Particle aerosol inward leakage test<br>• Limited liquid spray test (modified spray test) | • Permeation resistance<br>• Resistance to penetration by liquid under pressure<br>• Particulate penetration resistance<br>• Liquid penetration resistance<br>• Liquid repellency |

| | |
|---|---|
| Tensile strength | ISO 13934 – 1 |
| Tear (trapezoidal) resistance | ISO 9073-4 |
| Puncture resistance | ISO 13996 |
| Bursting strength | ISO 13938 – 1 |
| Abrasion resistance | ISO 12947-2 |
| Flex grading resistance | ISO 7854:1995 Method B |
| Resistance to flame | EN B 274-4: 2001 Method |

The ISO 16002:2007 (Table 10) addresses minimum requirements for protective clothing for protection against chemicals. Although, it is clearly mentioned in the standard that it does not addresses protection against biological hazards; ISO 16002:2007 can be used as guideline to develop new task / occupation specific standards along with above mentioned standards for diseases such as EVD, Avian flu, SARS etc. The ISO 16602:2007 classified clothing from 1a, 1b, 1c, 2, 3a, 4a, 5, 6[a] depending on type of chemical related hazard (

Table 10). The seams must be tested for strength, permeation resistance as well as penetration resistance (Table 11). Other than the above mentioned parameters, related requirement (

| **Integrity of whole chemical Protective clothing material** | **Chemical resistance of Protective clothing material** |
|---|---|
| • Leak Tightness<br>• Inward Leakage<br>• Liquid (Jet test) Penetration resistance<br>• Liquid (Spray test) penetration resistance<br>• Particle aerosol inward leakage test<br>• Limited liquid spray test (modified spray test) | • Permeation resistance<br>• Resistance to penetration by liquid under pressure<br>• Particulate penetration resistance<br>• Liquid penetration resistance<br>• Liquid repellency |

Table 12) also needs to be met as mentioned and classified in ISO 16602:2007.
It is also recommended to test antiviral activity of textiles. Antivirus activity of textile products can be determined according to ISO 8184 using one of the enveloped virus (influenza virus) and one of the non-enveloped virus (feline calciviurs). Considering the pathogenic nature of both viruses, the test must only be performed by trained laboratory personnel and at the laboratory meeting the legal requirements. The viruses are inoculated for a specific time on a reference sample and a test sample. . The remaining viruses are quantified after comparing the reference specimen and test specimen results using either plaque array or TCID50 method.

**Conclusion**

There are no virus specific standards available for PPEs at a single place (Appendix 4 indicates IAB recommendations for PPEs). Considering severity of disease such as EVD, Avian flu, SARS, etc, it is necessary to develop them for the benefit of the community. The above recommendations can be considered and new appropriate standards can be developed for PPEs against deadly disease causing microbes. This is only a guideline, so it is advisable to refer to respective standards for details of the method that is required to test conditions / atmospheric conditions, etc.

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