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# Design and Development of Face Masks

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**ABSTRACT**

Face mask and respirators are the major device which comes under both protective clothing and medical textiles. The design and development of such protective clothing is driven by the choice of materials, as defined by the social, psychological or physiological requirement of user, choice of technologies as defined by desired functionality; and ergonomic considerations, assembly methods, sizing and fit. This paper specifically reviews the facemask and respirators with respect to right selection of mask; functional, design and ergonomic requirements; product development and its characteristics; evaluation and test methods and few ongoing researches on filtration of nano sized particle.

***KEYWORDS:*** *Face masks, respirators, surgical mask and Filtration*

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## 1. INTRODUCTION

Filtration is a process that separates the components of a mixture. The mixture can be solid with solid, liquid with liquid, liquid with solid, and gas with solid. As per the Association of the Nonwovens Fabrics Industry (INDA), filtration is basically a process of separation and its basic objectives is to enhance the purity of filtered materials [1]. The textiles are main segment generally used for solid gas separation (dry filtration) and solid-liquid separation (wet filtration). Nonwoven filter media offer the possibility of collecting the particles on the filter surface and in the filter medium installation. Filter is a permeable medium designed to protect the wearer from dusts, fumes, vapours, bacteria and virus from air and liquid passing through it. Air pollution is one of the reasons among the major environmental hazard resulting in respiratory and cardiovascular diseases.

## 2. NECESSITY OF SOLID-GAS FILTRATION

Tiny solid particles (i.e. Dust) in the air, on the floor, and on process machinery can be dangerous for a human in number of ways. On average, the human eye cannot see particles that are smaller than 50 to 60 microns. Particles that are 10 microns or less are considered respirable and can settle deep into the lungs – often causing adverse health effect. 400 million unseen particles are present in one cubic foot of air in which 99% of the particles suspended in indoor air are too small to see. The average sizes of majority of these suspended particles are much smaller than 30 microns. A human weighs of 70kg, breathes 20 $m^3$ of air per day. This shows the importance of masks and respirator in personal protective equipment. The sizes of various particulate matter is shown in Figure 1.


**Figure 1 Sizes of various particles [3].**

### 2.1. Face mask and Respirators

Mask and respirators is a loose-fitting, disposable device that creates a physical barrier between the mouth/nose of the wearer and potential hazards in the immediate environment. The hazards may be from physical, electrical, heat, chemicals, biohazards, and airborne particulate matter. Face mask and respirators should give P1 and P2 protection which meets AS/NZS1716:2003 standard from mechanically generated particles and mechanically and thermally generated particles respectively. As per European directive 89/686/EEC, respiratory protective equipments like face mask and respirators are coming under Category III - 'Complex' designs PPE [4]

## 3. DESIGN AND DEVELOPMENT PROCESS FOR FACE MASK

### 3.1. Design process [2]

The design process to be followed for manufacturing of face mask is shown in Figure 2.

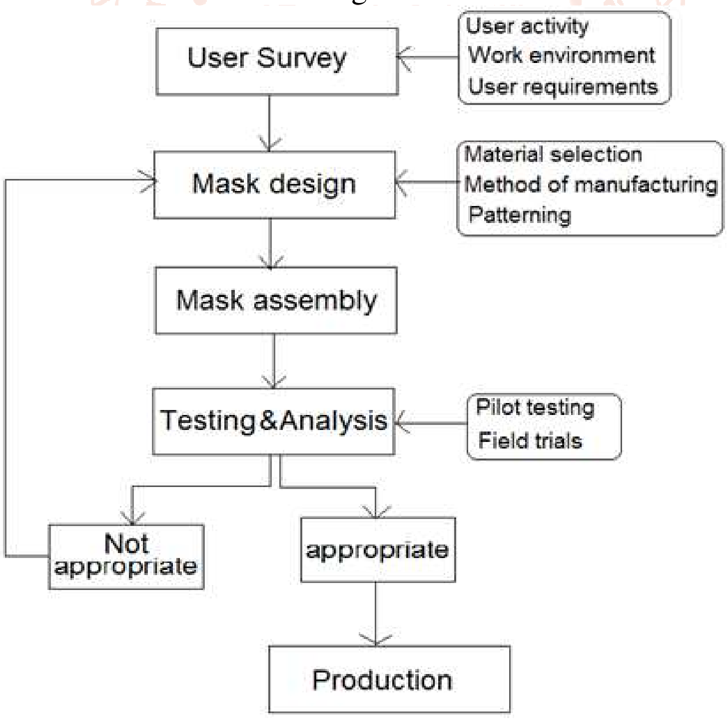


**Figure 2 Design process for face mask**

### 3.2. User Survey

#### 3.2.1. Classification of Face mask and Respirators

The face mask and respirators are mainly classified into two categories. i.e.

1. Based on the function
   – Comfort mask
   – Surgical face mask
   – Surgical Respirators
   – Particulate respirators

2. Based on usage
   - Disposable
   - Reusable

### 3.2.2. Right selection of masks

When selecting respirators, wearer must consider the chemical and physical properties of the contaminant, toxicity and concentration of the hazardous material and the amount of oxygen present [5]. Other selection factors are nature and extent of the hazard, work rate, area to be covered, mobility, work requirements and conditions, as well as the limitations and characteristics of the available respirators. The following flow chart will help to select the correct mask and respirators based on work environment.

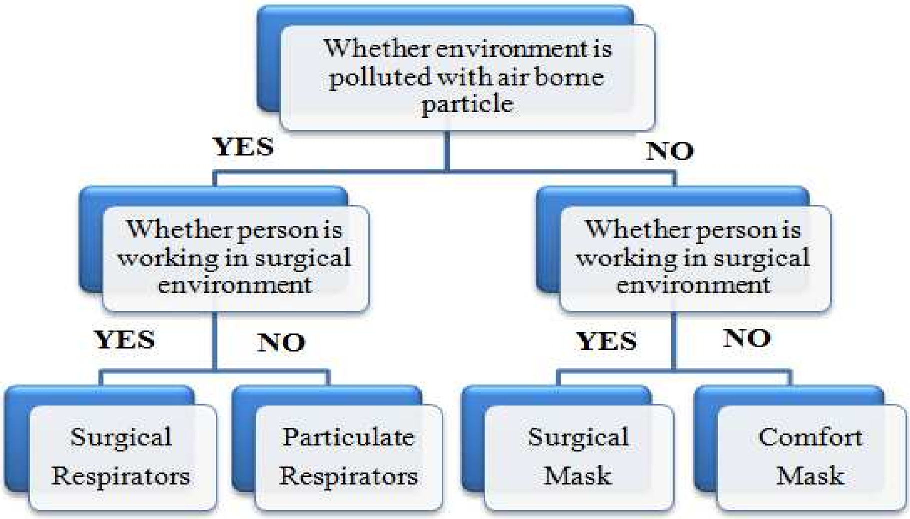


**Figure 3 Flow chart for proper selection of mask**

### 3.3. Mask Design

Non-woven are potentially better filters than woven as they are versatile, offer wide range of functionalities like smaller pore size, higher air permeability, improved cake separation and higher filtration efficiency especially in the submicron range aerosol filtration as well as being economical compared to woven media. Selections of fibre, method of making non-woven, number of layers, structure formation, and weight per unit area are chosen appropriately in order to fulfil the functional and design requirements. The high degree of filtration efficiency is attained with a very fine filter layer of textile fibres covered on both sides with conventional non-woven bonded fabrics. The thickness of fibre is from < 1 to 10 microns. Polypropylene, polystyrene, polycarbonate, polyethylene, polyester, viscose etc. are suitable for manufacturing face masks. The suitable polymers or fibres are converted as a non-woven sheet using needle punched or spun bonded or melt blown or electro statically produced web from solvents.

**Table 1 Merits and demerits of various nonwoven systems [6]**

| Structure | Merits | Demerits | Suitability |
|---|---|---|---|
| Dry laid | Higher strength Durability Higher thickness is possible More suitable for many fibres | Relatively large pore size Wider pore size distribution Not suitable for filtering fine particles | Suitable for all natural and man made fibres |
| Spun bonded | Random fiber structure. high opacity per unit area. Robust structure Modest dirt holding capacity Versatile structures possible range between 5 and 800gsm | Lack of precise pore size distribution | Suitable only for man made fibres Fiber diameters upto 50 micron (but preferred range is 15 – 35 micron) |
| Melt-blown | Random fiber orientation. Low to moderate web strength. Fine fibres from micro to nano scale is possible Random orientation of fibres offers greater filtration Low pressure drops Higher efficiency Range between 8 and 350GSM | Thin structures Lower manufacturing rates Relatively fragile structures | Thermoplastic polymers, Fiber diameters range between 0.5 and 30 micron but the typical range is 2-7 micron. |
| Electro spinning | Nano sized fibres are possible Higher filtration efficiency | Very thin structure Limited range of fibres are available Low manufacturing speed and flow rate | Solution of polymers |

### 3.3.1. Construction of face mask and respirators

Normally, mask and respirator contains 2 or 3 layers namely inner, middle and outer layer. Outermost layer is normally made up of spun bonded nonwoven with splash proof and filters out the largest dust particles. Middle layer is most responsible for filtration efficiency and filters maximum particle and made up of either needle punched or melt blown nonwoven technology. For additional filtration this layer may be made up with electro spun fibres. The innermost layer preserves the respiratory secretions and made up of spun bonded non-woven. The figure 4 shows the various layers of mask and respirators. The methods of electro statically produced web have uniform web density giving a high degree of filtration efficiency and less web weight [7].

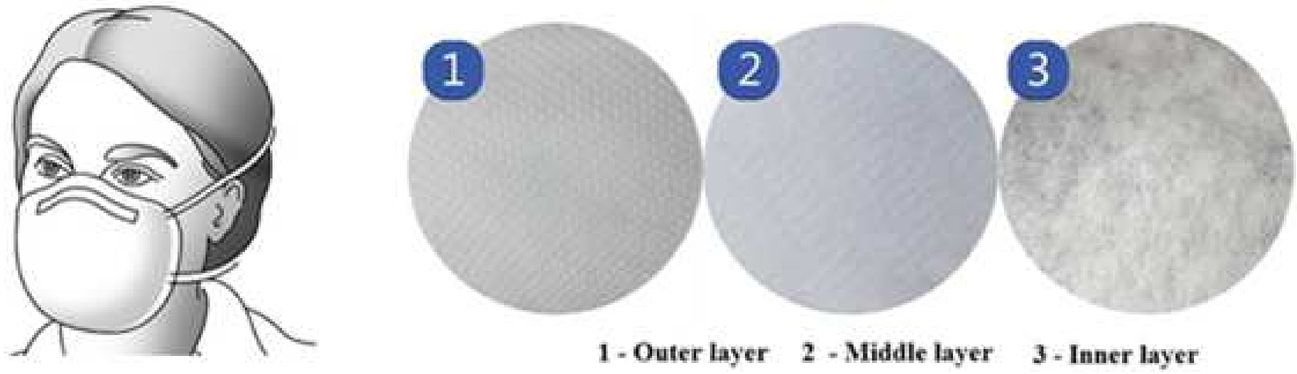


**Figure 4 Construction of face mask**

## 4. MATERIALS AND METHODS

It was planned to develop 3 layer face mask from 100% polypropylene fibres. The face mask consists of spun bonded inner and outer layer and needle punched nonwoven felt middle layer. The commercially available spun bonded nonwoven fabric of GSM 20 was purchased. For manufacturing middle layer, the DILO make fibre opener, roller clearer card, cross lapper and needle punching nonwoven machines were chosen. The fibres are fed to fibre opener where the fibres are pre-opened. Then the fibres are accumulated in reserve chute and then fed to roller clearer card. The process parameter of card are as follows: Cylinder speed:150 rpm, Doffer speed:15 mpm, Horizontal and vertical lapper speed:14.69 mpm, feed roller of needle loom:2.16 mpm, frequency of needle loom:216 strokes/min with 10mm advance per stroke. Totally, 10 layers of web were consolidated to make 80 GSM needle punched felt.

## 5. REQUIREMENT OF NANOSIZED PARTICLE FILTRATION

### 5.1. Filtration of nano particles by using melt blown technology

The size of many dangerous air pollutants (viruses, soot aggregates emitted by diesel engines, etc.) is of the order of nanometers, thus due to their size, they can easily penetrate through the human respiratory tract. It is therefore necessary to develop materials to effectively capture hazardous nano particles, either in the form of masks or protective clothing. The melt-blown technology allows to produce significantly larger quantities of fibers in a shorter time and at reduced cost. Raw materials used in this method were thermoplastic polymers with a high degree of polymerization, relatively low melt viscosity, and relatively small branching of their polymer chains. Those properties determine the so-called polymer spinnability, and their fulfilment guarantees high-capacity manufacture of high quality fibers. The arithmetic mean fibre diameter achieved through melt blown technology is 0.47 to 9.62 micron and tested for filtration efficiency with particle having diameter approx.20 to 200 nm and majority of them in the range between 30 nm to 60 nm [8]. The filtration efficiency of layer which have fibre diameter of 0.5, 5 and 10 micron are 91.19, 83.18 and 68.76 respectively. By reducing the fibre diameter in the filter, it is possible to increase the efficiency of filtration and also associated with higher pressure drop. It is evident that melt blown technology offers endless possibilities for developing filters of particular structure, and allows us to produce fibres with wide range of diameters, including nanometric fibres.

### 5.2. Filtration of nanoparticles by using needleless electro spun process

A small diameter and large surface area of nano fibres can be achieved by the electro spinning method. The needle electro-spinning has a very low production rate and the spinneret was frequently clogged during electro-spinning. Needleless electro-spinning appeared with the aim of producing nano fibres on a large scale. Numerous jets are formed simultaneously from the spinneret without the influence of capillary effect. Polyvinyl alcohol ($M_w$ -118000 g/mol) polymer solution is loaded into the stainless steel roller which has large number of jets [9]. The produced nano fibres with mean fibre diameters of ca. 100 nm were deposited on the nonwoven PP substrate which covered over the collector roller to form the composite filter. The composite was dried under vacuum condition to remove excess solvent.

Different composites were developed by changing concentrations of PVA solution (6 to 10 wt%) and tested for filtration efficiency with solid NaCl aerosols with number median diameter of 75+/-20 nm. The efficiencies of multilayer membranes are in the range of 99.60 to 99.78% and the same was compared with commercial HEPA filters under the same condition.

### 5.3. Nano silver incorporated electro-spun PAN fibres and spun bonded PP composites

Usage of the filter media are constantly subjected to attacks from environmental microorganism; the microorganisms that are readily captured over the filter grow rapidly; resulting in the formation of bio-films which deteriorate the quality of filtered air. Use of antimicrobial material over the filter will provide a solution for the above problem. Polyacrylonitrile (PAN) nanofibres are developed and made a composite filter with incorporated silver (Ag) nanoparticles sandwiched between two layers of spun bonded non-woven [10]. Aerosol filtration efficiency was performed using NaCl aerosol from 0.3 to 10 microns and antibacterial activity of developed filter were assessed against both gram positive Staphylococcus aureus and gram negative Escherichia coli bacteria. The maximum filtration efficiency of 99.3% is achieved for the sample has 0.846mm thick, 1.52 micron mean flow pore size. The inhibition zone of different lengths with increasing order was observed for PAN/Ag nanofibres with 5, 10 and 15 wt% of Ag. The increase in the inhibition zone length signifies the increase in the amount of Ag particles in the nanofibres.

## 6. ASSESSMENT AND STANDARDISATION OF FACE MASK

Protective facemask and respirators have to meet the defined requirements as mentioned in standard EN 149 (have classification FFP1, FFP2 and FFP3). Surgical masks are the device that gives barrier to minimise the direct transmission of infective agents between wearer and patient and also capture the infective components exhaled by the wearer. These masks have to meet the defined requirement as mentioned in standard EN14683 [11]. The performance levels of masks and respirators are to be evaluated on the basis of following criteria:

### 6.1. Assessment of test aerosol penetration (EN 143 & 149)

The penetration of aerosol particles through the filtration material is measured by the ratio of the aerosol particle concentration after and before passing the filter. Sodium chloride is used as test aerosol which is in dispersed solid phase. An aerosol of sodium chloride particles is generated from a 2% aqueous solution of reagent grade NaCl salt in distilled water [12]. The aerosol produced by this method is polydisperse with a mass mean particle diameter of approximately 0.6 micron. The percentage of aerosol particles that passed the filter, in relation to the total amount of particles fed to the tested object, is the criterion of assigning the filtration materials. Depending on the protection level, the filtration efficiency varies between 80 to 99.95%.

### 6.2. Bacterial filtration efficiency (ASTM F2101)

For surgical mask, bacterial filtration efficiency offers best evaluation method. The test aerosol is Staphylococcus Aureus as it has more clinical relevance and cause to nosocomial infections [13]. A bacterial challenged aerosol is passed through the test specimen either face side or inner side at a flow rate of 28.3 L/min. The mean particle size of the bacterial aerosol used in this test is maintained at 3.0±0.3 µm as per relevant ASTM specifications. Evaluation of filtration efficiencies related to both patient generated aerosols and wearer generated aerosols. Higher the BFE, higher protection level. Depending on the requirement of face mask, the filtering efficiency levels are ≥95% or ≥98%. Increased thickness of filtration layer, selection of fine diameter fibre and choosing the melt blown or electro spin fibres are the attempts to get higher BFE.

Classifications of surgical face masks as per BFE in European standard EN 14683 is as follows:

- BFE ≥ 95% indicates the Type-I surgical face masks
- BFE ≥ 98% indicates the Type-II surgical face masks.

### 6.3. Breathing resistance (ΔP) (BS EN 13274- 3 – 2001 & EN 143)

Delta P is used to determine the resistance of airflow through the facemask. It is the ratio of difference in pressure (pressure drop) to the surface area of the mask and expressed in $mmH_2O/cm^2$ or $Pascal/cm^2$. The face mask is subjected to controlled flow of air and difference in airflow pressure of inlet and outlet of the mask is measured. A lower in breathing resistance value per $cm^2$ indicates a better comfort level to the end user. Increasing the surface area of mask is the best attempt to reduce Delta P value.

Classifications of surgical face masks based on breathing resistance are as follows:

Type-I & II surgical face masks (non-splash resistant surgical face masks) ≤3.0 $mmH_2O/cm^2$.

Type-IR & IIR surgical face masks(splash resistant surgical face masks) ≤ 5.0 mm $H_2O/cm^2$

The air permeability of inner layer, middle layer, outer layer and combined 3 layers are 353 $cm^3/cm^2/sec$, 370 $cm^3/cm^2/sec$, 280 $cm^3/cm^2/sec$ and 134 $cm^3/cm^2/sec$ respectively.

### 6.4. Splash resistance (ASTM F1862-07)

This test determines the resistance of masks to the penetration resistance of the mask to fluids splash. A fixed volume of synthetic blood (stimulant fluid have equivalent liquid characteristics like surface tension of actual blood and other body fluids), is aimed at the specimen and dispersed at a known velocity. It simulates the impact of blood or other body fluid onto the specimen. Any evidence of synthetic blood penetration on the back side of the medical face mask constitutes failure. Specimen medical face masks are evaluated at a total of three different velocities corresponding to human blood pressures of 10.6, 16.0, and 21.3 kPa (80, 120 and 160 mm Hg). Higher the resistance, protection will be better.

Classifications of surgical face masks based on splash resistance in European standard EN 14683 are as follows: For Type-I and Type-II surgical face masks, this test is not applicable. For Type-IR and Type-IIR surgical face masks, the specimen should be tested under the constant velocity of 120 mm Hg

### 6.5. Flammability (16 CFR 1610)

There are many potential ignition sources in the operating room, including surgical lasers, electrosurgical units, endoscopic fiber optics and high-energy electro-medical devices. The materials used in operation theatre will burn if high intensity heat energy is applied to them, especially in the presence of elevated oxygen levels. Hence, the flammability test for surgical face masks is essential.

The standards given below are used to determine the flammability by class for medical device like surgical face masks (Guidance for Industry and FDA staff, 2004). Consumer Product Safety Commission (CPSC) 16 CFR 1610: Standard for flammability of clothing textiles; National Fire Production Agency (NFPA) Standard 702-1980: Standard for classification of flammability of wearing apparel. Underwriters Laboratory (UL) 2154: Fire test for surgical fabric. The flame spread characteristics are classified in terms of class 1 to class 4 for the above tests.

For NFPA, class 1 - slow burning, but as per CPSC standards, class 1 indicates that minimum of 3.5 sec or more required to ignite and spreading of flame on the specimen against the standard flame. In case of UL standards, test to measure the quantity of atmospheric oxygen required to propagate the flame while ignition is caused by an electro surgery unit or laser unit. Higher the LOI values better will be flame resistance.

## 7. CONCLUSION

Amongst various manufacturing methods, melt blown and electro spinning technology offers the excellent filtration capacity even for nano sized particles. A multilayer composite like nanofibres treated with spun bonded base layer has also shown the highest filtration efficiency about 99.95% for nano particle with low pressure drop. But still there is a challenge put forth in offering single mask for overall protection is not possible as the environment contains higher variation in particle distribution. Right selection of mask is the only best way to protection.

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