
## ABSTRACT.

More and more governments and organizations throughout the world are today recommending that wearing face masks in public should be mandatory. On June 5th, the World Health Organization (WHO) published an update recommending the use of a three-layered face mask — in a reverse of its former position on the matter. But the guidance given to the public on the types and use of face masks seems to be limited, and even confusing. Only France and Belgium have put preliminary regulations in place for non-medical community face masks. And while there is a large supply of all kind of face mask, it is hard for citizens to determine what is required of them during this pandemic.

Pactics has developed two models of FACEWEAR for use in different environments:

1) **Casual Model** - intended for use in public spaces. It will help to prevent the spread of the virus and serves as an addition to the recommended 2-meter / 6-foot social distancing rule.
2) **Business Model** - our recommended solution for all-day use in shared workspaces. This product allows employees who cannot always maintain social distancing to work comfortably and with consideration for the safety of those around them. It includes a filter pocket which holds a disposable filter for additional filtration (PFE 99% at 0.1 micron).

The Business Model is compatible with the WHO's recommendation on wearing three-layered face masks. In developing Pactics' FACEWEAR, all aspects of filtration efficiency, fit and comfort (respirability) were considered. The FACEWEAR comes in pairs — "Wear-One-Wash-One" — and includes an airtight washable pouch for easy storage and to avoid contact contamination.

## INTRODUCTION.

This new "2-meter / 6-foot society" in which we find ourselves today has generated a tremendous amount of debate around the use of face masks. Some believe they will not help — or simply feel uncomfortable about wearing them — while others are convinced that wearing one will help to protect them from the COVID-19 virus about which we still know so little. However, the medical world agrees that one of the ways the virus spreads is through airborne droplets released by coughing, sneezing or even speaking by a carrier. Social distancing is one of the fundamental recommendations put forward by health officials (combined with regular hand washing and avoiding touching your face with your hands) for helping to reduce exposure to the virus.

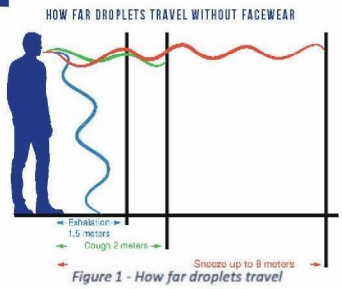


*Figure 1 - How far droplets travel*

Wearing a face mask minimizes the release of aerosols and at the same time limits the number of aerosols that you will breath in. It also reduces the risk of touching the area around your mouth with your hands (bearing in mind that infection can also occur by touching your eyes).

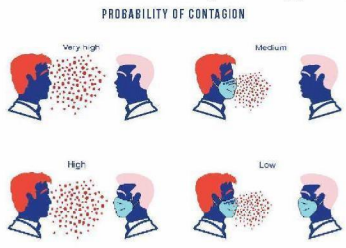


*Figure 2 - Probability of contagion.*

Although the science around the effectiveness of face masks is not yet definitive, the greater agreement is that they do offer some protection from the virus. The Centers for Disease Control and Prevention (CDC) recommends that people use a simple cloth face covering when they go out, while WHO recommends the use of a triple-layered face mask with a filter. While stocks are still inadequate, medical face masks should be reserved for those who need them the most: healthcare professionals and first responders.

Face masks were already very common in Asia before the outbreak of this pandemic. People were accustomed to wearing them, and they were widely available. Places like Hong Kong and Taiwan with very dense populations never went into a full lock-down and have reported a fraction of the cases and deaths from the virus compared to, for example, New York. Many attribute this difference to the habitual wearing of masks by large parts of the population.

## WHAT TYPE OF FACEMASK TO USE DURING THE CORONA PANDEMIC?

Choosing the right type of face mask depends on the kind of the environment a person is going to be in. For example, healthcare professionals (HCPs) working with COVID-19 patients have different requirements from someone on a shopping trip. For the HCP, regulations on high-grade PPE products and their uses in different healthcare contexts are well documented. For the non-HCP, however, less guidance is available.

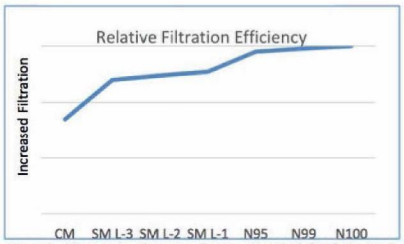


*Figure 3 - Comparison between Community Mask (CM), Surgical Masks (SM) and Respirators (N95, 98, 100)*

Moreover, the WHO, CDC and many governments have recommended or made the use of non-medical face masks mandatory in certain public spaces without giving much detail on the requirements, with the result that a short trip on public transport will reveal the use of a wide variety of options, from simple homemade to industrially produced masks.

Only France and Belgium have so far issued firm regulations for community masks that set a minimum level of PFE of 3 microns at 70% and respirability or Delta P at > 70 Pa/cm2 (or > 7.1 mmH2O/cm2), both measures based on EN 14683:2019.

For a long time, the WHO rejected the use of face masks as a protective measure by the public. They have recently however changed their position. The organization now recommends that members of the public wear a "face mask that consists of at least three layers of different materials: an inner layer being an absorbent material like cotton, a middle layer of non-woven materials such as polypropylene (for the filter) and an outer layer, which is a non-absorbent material such as a polyester or a polyester blend ."Nonetheless, no minimum requirements on respirability or filtration efficiency have been provided. There are as yet no recommendations relating to the use of face masks in non-medical work environments. Yet as national economies have gradually opened in recent weeks, many workers are finding themselves in situations where maintaining social distancing is difficult if not impossible. In that context, a non-medical Business Model mask with three layers (as per WHO recommendation) and a filter that provides a minimum PFE of 0.3 microns > 80% and a Delta P < 3 mm H2O / cm2 would be the best solution for such workers. The Pactics' Business Model's fills this gap between simple community masks and surgical -grade masks with a filtration requirement that is higher than for community masks (AFNOR and NBN regulation require a PFE at 3.0 micron of >70%) to help workers continue working with a greater degree of security even where recommended social distancing is not possible. (see Figure 4)

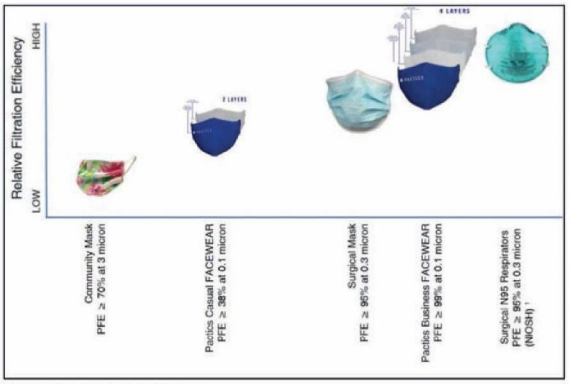


*Figure 4 - Relative Filtration Efficiency*

## FILTRATION OF THE FACEMASK

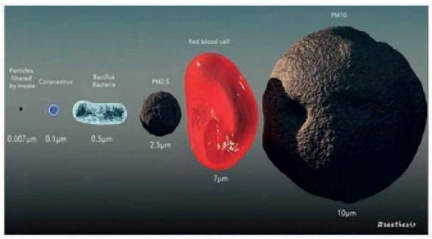


*Figure 5 - Particle Sizes*

Face masks are designed to filter (capture) particles from the air and prevent them from entering the respiratory system while allowing the wearer to continue breathing independently. A mask's filtration efficiency is measured against its ability to capture active (bacterial) and non-active particles (including viruses). Bacterial Filtration Efficiency (BFE) measures a mask's ability to capture active particles of 3 microns, while Particle Filtration Efficiency (PFE) measures its ability to capture inactive particles of 0.1 to 0.3 microns. Medical face masks are also splash resistant in order to protect against patients' bodily fluids.

However, high filtration capacity tends to lower a mask's respirability, which is measured by Delta Pressure or Flow Rate.

It is important to understand that the FDA / CEN filtration test for medical masks based on ASTM 2100 US / EN 14683 and the NIOSH / filtration tests for respirators based on 42 CFR Part 84 US / EN149:2001 will yield different results for the BFE at 3.0 microns and the PFE at 0.3 microns. NIOSH uses a NaCl aerosol test method for PFE and paraffin oil for BFE. The FDA ASTM uses 0.3 microns size polystyrene latex particles for PFE and 3.0 microns size particles containing bacteria for BFE. The FDA / ASTM testing shows no significant difference in filtration efficiencies for respirators compared the NIOSH testing. For surgical masks, the NIOSH testing show however only half of the filtration efficiencies compared the FDA tests for the same masks.

What level of filtration required for use in the workplace and for use in public places? The ANFOR norm in France recommends a PFE of >70% at 3 microns for community face masks intended to be worn by the public while in public spaces (such as public transportation).

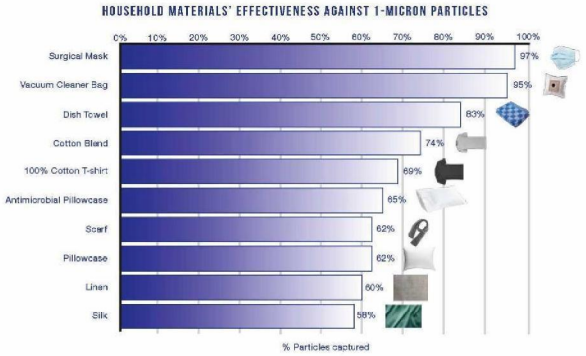
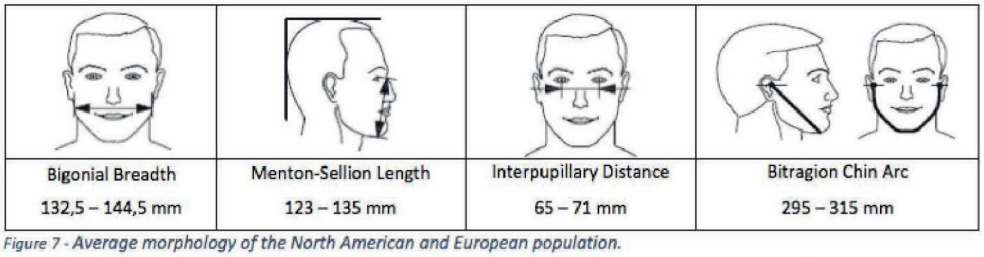



*Figure 6 - Household Materials PFE at 1 microns*

The WHO recommends Level 1 Surgical Masks for healthcare professionals in screening and triage intake points. These masks have a PFE at 0.3 microns and a BFE at 3.0 microns of ⊠95%. There are no corresponding recommendations for non-healthcare professionals for whom social distancing in the workplace is not always possible, for example hotel front desk personnel, supermarket cashiers, restaurant waiters, hairdressers, etc. Medical masks need to stay reserved for HCPs. However, non-medical masks that nonetheless have a filtration efficiency close to that of surgical masks could be a valuable alternative for those professionals. Figure 6 shows the PFE at 1 micron for different household materials. Dishcloths and vacuum cleaner bags have a PFE close to surgical masks, but the respirability is so low that these materials cannot be used for a face mask.

## FIT OF THE FACEMASK

The fit of the face mask is critical for efficient filtration. When it is loose air can leak or escape from different sides without being filtered. Thus masks need to be sized to suit the average morphology of the target population.



| Bigonial Breadth | Menton-Sellion Length | Interpupillary Distance | Bitragion Chin Arc |
|---|---|---|---|
| 132,5 – 144,5 mm | 123 – 135 mm | 65 – 71 mm | 295 – 315 mm |

*Figure 7 - Average morphology of the North American and European population.*

The face mask needs to be large enough to cover the nose and mouth from underneath the chin to the top of the nose where a "nose bridge" (metal strap) helps to hold it in place. Finally the sides should fit snugly over both cheeks.

The mask should be "cup formed" rather than flat in order to allow it to follow the face's natural contours, and adjustable straps can make sure that it can be adapted to different sizes within the morphology of the target population.


*Figure 8 - Correct Fit*

## HOW TO PROPERLY TAKE CARE OF A FACEMASK

Viral particles remain infectious for different periods of time depending on the surface and environment they are in. On common surface materials, such as ceramic tiles, glass, and stainless-steel, it has been found that coronavirus can remain infectious for up to several days. On porous surfaces like cotton and polyester fabrics, wood, paper and tissue, the virus can survive for 8 to 12 hours. At higher temperatures and humidity (38°C and relative humidity above 95%) the virus viability rapidly decreased. In an air-conditioned environment, the virus can survive for as much as two weeks, and longer.

This means that when you take off your mask, after a journey on public transportation for example, it is possible that the mask is carrying particles of the virus it has picked up en route. It is therefore important not just to stow the mask away with other articles in one's pocket or purse etc., but to store it in an airtight container to avoid cross-contaminating other items. Cleaning hands with water and soap or a hand sanitizer that is at 70% alcohol is also critical. Cleaning the outside of the storage bag with an alcohol wipe is also highly recommended. The storage bag supplied with the Pactics face masks should be cleaned with a normal detergent at 65oC (150oF) for a minimum of 30 minutes after each use.

## TYPES OF FACEMASKS

Three basic mask types (or certification types) are available on the market

1. Community Masks -> regulated in France (AFNOR SPEC S76-001) and Belgium (NBN/DTD S 65-001:2020), and other countries will probably follow suit.
2. Industrial Masks -> regulated by NIOSH (National Institute for Occupational Safety and Health) in the USA and the EU-OSHA (European Agency for Safety and Health at Work) in the EU.
3. Medical Masks -> regulated by the FDA (Food & Drug Administration) in the USA and the EMA (European Medicines Agency) in Europe.

The requirements, specifications and testing methods vary according the type of mask in question.

Figure 9 - Community Mask

Community masks, the least regulated, have low requirements for filtration and respirability (for details see Table 1 in the Appendix). A wide variety of these masks is now available ranging from simple (home-made), single-layer masks to those with disposable filters or special "pollution" filters (PM2.5 filters) which include a valve that works to filter only air that is inhaled by the wearer. For this reason, these masks limit the level of protection afforded to those around the wearer and should not be used.


Figure 10 - Community Mask with Valve


Figure 11 - N95 Respirator with Valve

Industrial masks are also available in a wide variety with and without external air sources. This document limits the description of industrial masks to disposable respirators. Respirators are available in two basic versions with and without a valve. There are ten classes of NIOSH-approved particulate filtering respirators. The minimum level of filtration approved by NIOSH is 95%. The N, R and P designations refer to the respirator's oil resistance as described below.


Figure 12 - N95 Industrial Respirator

| Filter Class | | | Particle Filtration at 0.3 microns | | | Resistance to Oil |
|---|---|---|---|---|---|---|
| N95 | N99 | N100 | ≥ 95% | ≥ 99% | ≥ 99.97% | Not |
| R95 | R99 | R100 | ≥ 95% | ≥ 99% | ≥ 99.97% | Resistant |
| P95 | P99 | P100 | ≥ 95% | ≥ 99% | ≥ 99.97% | Oil-Proof |

Figure 13 - Filtration for different classes of Respirators

Medical Masks cover two types: surgical masks and medical respirators:

1. Surgical Masks -> (also called 3-ply masks) generally fit loosely over the nose and mouth and are used inside the operating theater or direct sterile environments where protection from germs coming from the person wearing the mask (inside-outside protection) is required. The product is made of three layers of non-woven melt-blown material. For medical purposes, the splash resistance is important because during certain medical procedures patients' bodily fluids can spill towards the wearer of the mask. The outer layer has hydrophobic properties to create splash resistance, the middle layer filters and the inner layer adsorbs breath vapor. Technical standards, which differ slightly between the US and the EU, are published by ASTM International (ASTM F2100-11) for the US and CEN (EN 14683) in Europe. Surgical masks are made to perform at three levels, the main difference between them being the splash resistance. Details on the standards are provided in Table 2 in the Appendix.


Figure 14 - Medical N95 Respirator

2. Respirators -> Originally developed for industrial use only to protect the wearer from hazardous fumes, dust etc., (outside-inside protection). Respirators have been modified for use in the medical field as well as in highly contagious contexts and laboratories. In the US these are called surgical N95s, and in Europe FFP (Filtering Face Piece). Medical and industrial respirators are similar in appearance with key differences in the fluid resistance and the resulting FDA / EMA clearance of surgical N95s / FFPs. Standards for respiratory masks in Europe are regulated by EU-OSHA (European Agency for Safety and Health at Work) under the European Standard EN149:2001. This provides for three classes of protection against solids, water-based aerosols: FFP1, FFP2, and FFP3. In the US, NIOSH is responsible for the certification and approval of respiratory protective devices for occupational use. Only those that meet or exceed all the requirements established in the 42 CFR Part 84 standards are acknowledged by the agency.

*Picture: 6 Medical N95 Respirator*

The FDA defines a Surgical N95 Respirator as a single-use, disposable respiratory protective device (RPD) to protect both the patient and healthcare professional at an N95 filtration efficiency level per 42 CFR 84.181. A surgical N95 respirator is a class II device, regulated by FDA under 21 CFR 878.4040 (FDA product code MSH). Details on the standards are provided in the Table 3 in the Appendix.

## CONCLUSIONS:

Properly fitted respirators give the wearer the highest level of protection while, when used without an exhalation valve, also preventing spread of the virus from the wearer. They are disposable devices with low respirability that should not be used for more than eight hours, and become uncomfortable for the wearer even after a few hours' use. When used for a number of days in a row, respirators can irritate the skin, as we have seen from media images of healthcare workers over the last few months. Made from plastic, these disposable devices also exact a damaging toll on the environment. Moveover, over the course of the pandemic, their price has quadrupled and they have been difficult for many authorities and organizations to source.

*Figure 15 - HCP after wearing N95*

Surgical masks help to prevent the spread of the virus but, if loosely fitted, provide very little protection to the wearer. They are also plastic and disposable, should not be worn for more than four hours at a time, difficult to come by and expensive if one needs to wear two or more a day.

There is still a shortage of PPE for HCPs and first responders. As a result, the CDC, WHO and national governments advise the public not to wear surgical masks or respirators in order to reserve the available capacity for those who need it most.

*Figure 16 - Pactics FACEWEAR*

People who cannot always maintain a 2-metre / 6-foot distance in their working environment should follow the WHO recommendation for a triple-layered mask with a filter and a cup form (i.e. not flat) in order to provide a good fit. Pactics believes that the best options for the non-HCP is to use the reusable (washable) Business Model FACEWEAR. This is why:

1. Pactics' FACEMASK offers significantly easier respirability while also providing better protection against catching or spreading the virus than a one- or two-layered cloth alternative;
2. Washable Business Model face masks are more cost effective than disposable medical masks;
3. They help to protect the environment.
4. They leave medical masks for those who need them most.

For those who can maintain social distancing, a washable, well-fitting two-layered mask is a good option, and Pactics' Casual Model FACEWEAR is now available in a range of fashionable designs that look significantly better than the blue medical masks.

## REFERENCES:


- Davies, (10)(2e), K., Giri, K., Kafatos, G., Walker, J., & Bennett, A. (2013). Testing the Efficacy of Homemade Masks: Would They Protect in an Influenza Pandemic? Disaster Medicine and Public Health Preparedness, 7(4), 413-418. doi:10.1017/dmp.2013.43
- 3M Science Applied to Live – Technical Bulletin March 2020 – Revision 2
  Surgical N95 vs. Standard N95 – Which to Consider?
- Nelson Labs
  Medical Face Mask Test Requirements
- ANFOR Groupe
  AFNOR Spec - Barrier masks V1.0
- Samy Rengasamy, Ronald Shaffer, Brandon Williams, and Sarah Smit
  A comparison of facemask and respirator filtration test methods
- Belgisch technisch document - NBN/DTD S 65-001:2020
  Community- en Artisanale maskers - Gids van de minimale vereisten, confectie, onderhoud en gebruik
- World Health Organization: Interim guidance 5 June 2020
  Advice on the use of masks in the context of COVID-19
- The New England Journal of Medicne - N Engl J Med 2020; 382:1564-1567 DOI: 10.1056/NEJMc2004973
  Aerosol and Surface Stability of SARS-CoV-2 as Compared with SARS-CoV-1


## APPENDIX

Community Masks – Test Requirements.

| Test | ANFOR S76-001 | NBN/DTD S 65-001:2020 |
|---|---|---|
| | Barrier Mask EN 13274-7, sec 6 [1] or sec 7 [2] | Community Mask EN 14683:2019 |
| Splash Fluid Resistance mmHg | not required | not required |
| BFE s 3 micron, % | not required | ≧ 70 [3] |
| PFE at 3 microns, % [3] | ≧ 70 | ≧ 70 or [3] ≧ 30 EN 149+A1:2009 [3] |
| Delta P, mm H2O / cm2 | < 6.20 | < 7.1 |
| Flammability | not required | not required |
| Microbial cleanliness (cfu/g) | not required | not required |

*Table 1: Test Requirements for Community Masks.*

*[1] Sodium Chloride test method or [2] Paraffin Oil test method (only one of the 2 PFE tests is required)*

*[3] Only one of the 3 tests are required BFE, PFE (based on EN14683:2019 or PFE based on EN149+A1:2009)*

- **Splash Fluid Resistance** reflects the mask's ability to minimize the amount of fluid that could transfer from the outer layers through to the inner layer as the result of a splash or spray.
- **BFE (bacterial filtration efficiency)** measures how well the mask filters out bacteria.
- **PFE (particulate filtration efficiency)** measures how well a mask filters sub-micron particle with the expectation that viruses will be filtered in a similar manner.
- **Delta P (pressure differential)** measures the air flow resistance of the mask and is an objective measure of breathability in Pa or mm/H2O ((1 Pa – Pascal = 0.10 mm/H2O)
- **Flammability USA:** masks must withstand exposure to a burning flame (within a specified distance) for three seconds. (NIOSH 42 CFR 84 USA – Class 1)
- **Flammability EU:** masks are passed one by one through a flame with a temperature of 800°C +/- 50°C and at a speed of 6 cm/s. The respirators must not go on burning for more than 5 s after removal from the flame. (EN149:2001+A1:2009 EU – Pass)
- **Microbial cleanliness (cfu/g):** The Microbial Cleanliness test determines the total number of viable microorganisms on the face mask using an extraction method. Based on the weight of the mask, the results are reported as the total bioburden per gram tested for each mask.

Additional Requirements for ANFOR S76-001 and NBN/DTD S 65-001:202

1. Visual Inspection – by the manufacturer or the test laboratory.
2. Verification of the tensile strength of the head harness is done by putting and removing the mask 5 times on at least 3 test subjects with different morphologies.
3. The test protocol must be conducted on 3 samples after the number of washes specified by the manufacturer.
4. Materials that come in contact with the user's skin shall not present known risk of irritation or adverse effects on health. Materials that may release irritating substances into the inhaled air shall not constitute a hazard or nuisance for the user.
5. Marking and information / instructions:
   The mask shall be clearly, and durable marked on the smallest marketable package available or shall be legible through the packaging if the packaging is transparent.

   - The name, trademark, or any other means of identification of the supplier.
   - The visible wording ANFOR S76-001 and "Barrier mask" /
   - The recommended period of use for the barrier mask.
   - The cleaning instructions (number of washes, washing and drying method).
   - The following instructions: "this is not a medical device in the sense of Regulation EU/2017/745 (surgical mask) nor is it a personal protective equipment in the sense of Regulation EU/2016/425 (filtering mask type FFP2)."
   - A pictogram of how to put the barrier mask in place may be substituted for instructions

Surgical Masks – Test Requirements.

| Test | EN 14683:2014 (EU) | | | ASTM F2100 (USA) | | |
|---|---|---|---|---|---|---|
| | Type I | Type II | Type IIR | Level 1 | Level 2 | Level 3 |
| Splash Fluid Resistance mmHg | not required | not required | 120 | 80 | 120 | 160 |
| BFE at 3 microns, % | ≧ 95 | ≧ 98 | ≧ 98 | ≧ 95 | ≧ 98 | ≧ 98 |
| PFE at 0.3 micron, % | not required | not required | not required | ≧ 95 | ≧ 98 | ≧ 98 |
| Delta P, mm H2O / cm2 | < 3.00 | < 3.00 | < 5.00 | < 4.00 | < 5.00 | < 5.00 |
| Flamability | not required | not required | not required | Class 1 | Class 1 | Class 1 |
| Microbial cleanliness (cfu/g) | ≦ 30 | ≦ 30 | ≦ 30 | not required | not required | not required |

*Table 2: Test Requirements for Surgical Mask.*

- **Splash Fluid Resistance** reflects the mask's ability to minimize the amount of fluid that could transfer from the outer layers through to the inner layer as the result of a splash or spray.
- **BFE (bacterial filtration efficiency)** measures how well the mask filters out bacteria.
- **PFE (particulate filtration efficiency)** measures how well a mask filters sub-micron particle with the expectation that viruses will be filtered in a similar manner.
- **Delta P (pressure differential)** measures the air flow resistance of the mask and is an objective measure of breathability in Pa or mm/H2O ((1 Pa – Pascal = 0.10 mm/H2O)
- **Flammability:** masks must withstand exposure to a burning flame (within a specified distance) for three seconds. (NIOSH 42 CFR 84 USA – Class 1)
- **Flammability:** masks must withstand exposure to a burning flame (within a specified distance) for three seconds. (NIOSH 42 CFR 84 USA – Class 1)
- **Flammability:** masks are passed one by one through a flame with a temperature of 800°C +/- 50°C and at a speed of 6 cm/s. The respirators must not go on burning for more than 5 s after removal from the flame. (EN149:2001+A1:2009 EU – Pass)
- **Microbial cleanliness (cfu/g):** The Microbial Cleanliness test determines the total number of viable microorganisms on the face mask using an extraction method. Based on the weight of the mask, the results are reported as the total bioburden per gram tested for each mask.

Surgical Respirators – Test Requirements

| Test | EN149:2001+A1:2009 (EU) | | | NIOSH 42 CFR 84 (USA) + FDA 21 CFR 878.4040 (USA) | | |
|---|---|---|---|---|---|---|
| | FFP1 | FFP2 | FFP3 | N95 | N99 | N100 |
| Splash Fluid Resistance mmHg | not required | not required | 120 | 80 / 120 /160 | Not Available | Not Available |
| Inward Leakage, % | ≦ 25 | ≦ 11 | ≦ 5 | not required | not required | not required |
| BFE at 3 microns, % | not required | not required | not required | not required | not required | not required |
| PFE at 0.3 microns, % NaCL and Paraffin | ≧ 80 | ≧ 94 | ≧ 99 | ≧ 95 | ≧ 99 | ≧ 99.97 |
| Breathing Resistance Inhalation, Pa | ≦ 210 | ≦ 240 | ≦ 300 | ≦ 343 | ≦ 343 | ≦ 343 |
| Flow Rate l/min | 95 | 95 | 95 | 85 | 85 | 85 |
| Breathing Resistance Exhalation, Pa | ≦ 300 | ≦ 300 | ≦ 300 | ≦ 343 | ≦ 343 | ≦ 343 |
| Flow Rate l/min | 160 | 160 | 160 | 85 | 85 | 85 |
| Flammability | Pass | Pass | Pass | Class1 | Class1 | Class1 |
| Microbial cleanliness (cfu/g) | ≦ 30 | ≦ 30 | ≦ 30 | not required | not required | not required |

*Table 3: Test Requirements for Medical Respirators.*

- **Splash Fluid Resistance** reflects the mask's ability to minimize the amount of fluid that could transfer from the outer layers through to the inner layer as the result of a splash or spray.
- **Inward Leakage is tested in 3 ways:** face seal leakage, exhalation valve leakage (if exhalation valve fitted) and filter penetration. Ten test subjects wearing the respiratory conduct a series of exercises inside a test chamber containing an aerosol of Sodium chloride and the amount of the test aerosol inside the respiratory is measured.
- **BFE (bacterial filtration efficiency)** measures how well the mask filters out bacteria
- **PFE (particulate filtration efficiency)** measures how well a mask filters sub-micron particle with the expectation that viruses will be filtered in a similar manner.
- **Breathing Resistance Inhalation** measures the resistance that the mask cause at inhalation at a certain flow rate of air. (1 Pa – Pascal = 0.10 mm/H2O)
- **Breathing Resistance Exhalation** measures the resistance that the mask cause at exhalation at a certain flow rate of air.
- **Flammability US:** masks must withstand exposure to a burning flame (within a specified distance) for three seconds. (NIOSH 42 CFR 84 USA – Class 1)
- **Flammability EU:** masks are passed one by one through a flame with a temperature of 800°C +/- 50°C and at a speed of 6 cm/s. The respirators must not go on burning for more than 5 s after removal from the flame. (EN149:2001+A1:2009 EU – Pass)
- **Microbial cleanliness (cfu/g):** The Microbial Cleanliness test determines the total number of viable microorganisms on the face mask using an extraction method. Based on the weight of the mask, the results are reported as the total bioburden per gram tested for each mask.