

Masks: which? When? How long? For whom?

Masks have become one of the most sought items with the COVID epidemic as wearing mask is **one** of the protective measure against COVID infection. But masks should be used as part of a comprehensive strategy of measures (hand hygiene, physical distance respiratory etiquette) to suppress transmission and save lives; the use of a mask alone is not sufficient to provide an adequate level of protection against COVID-19

In general, masks are used by the general public and health care personnel to prevent the spread of infection or illness.

But looking at the wearers, it is questionable whether they have a proper understanding of wearing masks.

It is very important to know about any equipment if we want to get the maximum benefit out of it.

We generally use the word “mask” to name “respirators” & “masks” both. Masks & respirators are used in different settings for different indications (chart 1). But this article targets the masks used to prevent infections.

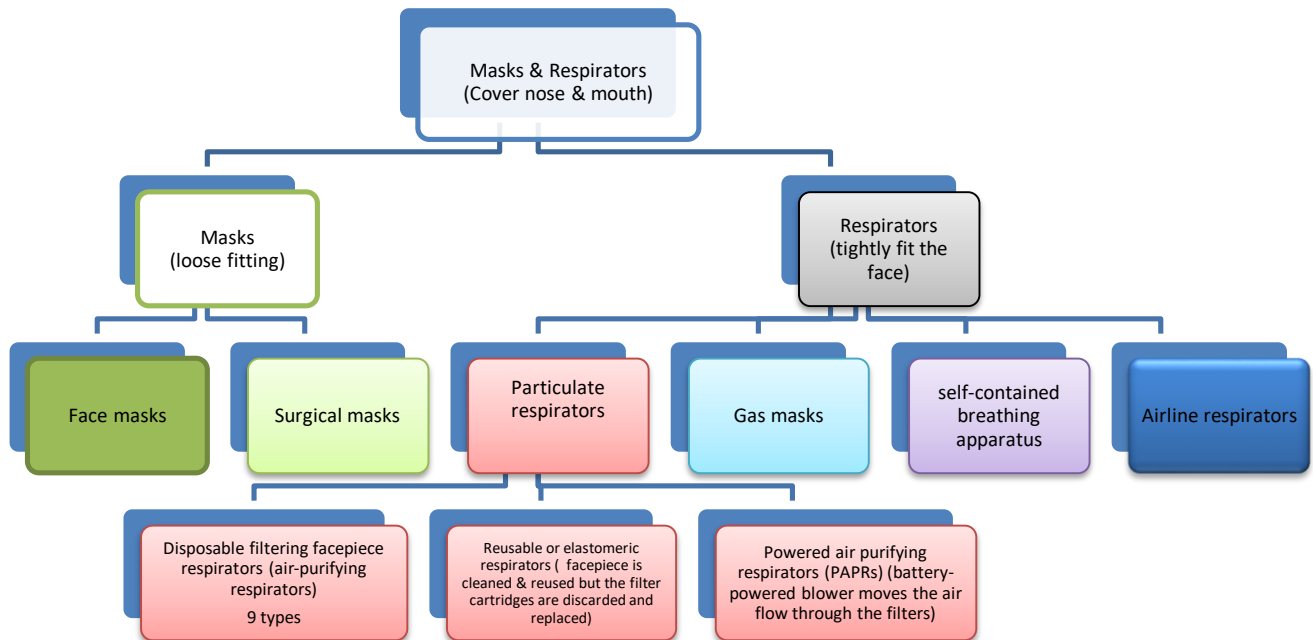


Chart 1 – Masks & respirators





| | | | |
|---|---|--|---|
|  |  |  |  |
| Picture -1 Medical/Surgical mask | Picture -2 N95 respirator | Picture -3 Elastomeric respirators | Picture -4 Powered air purifying respirators |

Table 1 – Guide to masks & respirators

| | Face mask (cloth or paper masks) | Surgical/medical mask | N95 respirator | Surgical N95 respirator (medical respirator) |
|------------------------------------|--|---|---|---|
| Is it a medical device? | No | Yes | No | Yes |
| Purpose | Prevents large particles expelled by you, the wearer, from reaching the environment. | Prevents large particles expelled by you, the wearer when you are ill, from reaching the environment. To be used as a physical barrier to protect you from large droplets of blood or body fluids. | Reduces your exposure to very small airborne particles or contaminants. May not protect against sprays and direct liquid splashes. | Provides the protection of both a surgical mask and N95 respirator. To be used as a physical barrier from large droplets of blood or body fluids as well as very small particles (e.g. fine aerosolised droplets), such as those produced by coughing. |
| Fit | Does not fit tightly | Does not fit tightly | Tight fit | Tight fit |
| Filtration efficiency | Does not fit tightly | Bacterial filtration efficiency above 95%*(EN | Equal or above 95% (NIOSH) against | Equal or above 95% (NIOSH) against particulate aerosols (of |

| | | | | |
|--|---------------------|-------------|--|----------------------------------|
| | | 14683:2005) | particulate aerosols (of 0.3 micron in size) free of oil | 0.3 micron in size) free of oil. |
| Fluid resistance (resistance to penetration of body fluids) | Not fluid resistant | Yes | Not tested for fluid resistance | Tested to be fluid-resistant |

Masks and respirators both cover a wearer’s nose and mouth, but they differ in several aspects.

Masks are loose fitting and may not provide full protection from breathing in airborne pathogens, such as viruses.

Face Masks:

- Face masks (non-surgical masks) may not provide protection from fluids (liquid barrier protection) or may not filter particles, needed to protect against pathogens, such as viruses. During the COVID-19 public health emergency, a face masks (including cloth face coverings recommended by the Centers for Disease Control (CDC)) are used for a “medical purpose” as a source control measure (protect others from a patient). They are not for surgical use and are not considered personal protective equipment. It may be for single or multiple uses, and if for multiple uses it needs to be laundered or cleaned.

The face masks include labeling that:

- Accurately describes the product as a face mask (as opposed to a surgical mask or filtering facepiece respirator);
- Includes a list of body-contacting materials (which does not include any drugs or biologics); and
- Includes recommendations and general statements that would reduce the risk of use

Surgical Masks

- Surgical masks usually consist of three layers of flat or pleated fabric. They are fluid-resistant, disposable, and loose-fitting devices that create a physical barrier between the mouth and nose of the wearer and the immediate environment. The key performance requirement is fluid resistance.

- Mask provides the wearer protection against large droplets, splashes, or sprays of bodily or other hazardous fluids. Protects others from the wearer's respiratory emissions. It does NOT provide the wearer with a reliable level of protection from inhaling smaller airborne particles (airborne pathogens, such as viruses) and is not considered respiratory protective. (Regulated under 21 CFR (878.4040 Code of Federal Regulations –FDA) as class II devices) Additionally, these masks meet certain fluid barrier protection standards and Class I or Class II flammability tests. (Table 2)
- For health workers, medical masks are essential personal protective equipment when engaging with patients with suspected, probable or confirmed COVID-19.
- A procedure mask is used for performing patient procedures, or when patients are in isolation to protect them from potential contaminants. Procedure masks are used to protect both patients and staff from the transfer of respiratory secretions, fluids or other debris. Procedure masks are used for generally "respiratory etiquette" to prevent clinicians, patients and visitors from spreading germs by talking, coughing, or sneezing. They have ear loops for quick donning, and since they do not slide on the hair, they can be worn without a surgical cap.
- ASTM (American Society of Testing and Materials) is an international standards organization that develops and publishes voluntary consensus technical standards for a wide range of materials, products, systems, and services—including those in healthcare)

The current standard ASTM F2100-11 (2011) specifies the performance requirements for Medical Face Masks with five basic criteria:

1. **BFE (Bacterial Filtration Efficiency):** In order to be called a medical/surgical mask, a minimum 95% filtration rate is required. Moderate and high protection masks must have bacterial filtration rates greater than 98%.
2. **PFE (Particulate Filtration Efficiency):** PFE measures how well a hospital mask filters sub-micron particles with the expectation that viruses will be filtered in a similar manner. ASTM F2100-11 specifies that a particle size of 0.1 micron be used. When comparing test results it is important to note the size of the test particles used, as use of a larger particle size will produce a misleading PFE rating.
3. **Fluid Resistance:** Fluid resistance reflects the surgical 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. ASTM specifies testing with synthetic blood at

pressures of 80, 120, or 160 mm Hg to qualify for low, medium, or high fluid resistance.

4. **Delta P (Pressure Differential):** Delta P measures the air flow resistance of the medical mask and is an objective measure of breathability. The ASTM standard requires that masks have a Delta P of less than 5.0 for moderate and high barrier masks, whereas low barrier masks must have a Delta P of less than 4.0.
5. **Flame Spread:** As hospitals contain sources of oxygen, heat, and fuel the ASTM F2100-11 standards include testing for flame resistance. Testing dictates that all hospital masks must withstand exposure to a burning flame (within a specified distance) for three seconds.

5.5 **ISO Certification:** In addition to the above tests, all medical face masks must be tested to an international standard (ISO 10993-5, 10) for skin sensitivity and cytotoxic tests to ensure that no materials are harmful to the wearer.

There are three unique levels of protection with ASTM-rated medical masks. Level 1 masks have the lowest barrier of protection, while Level 3 masks have the highest barrier of protection. (Table 2 & 3)

Table 2 - ASTM levels of masks

| LEVEL 1 (LOW) BARRIER: 80 mm Hg | LEVEL 2 (MODERATE) BARRIER: 120 mm Hg | LEVEL 3 (HIGH) BARRIER: 160 mm Hg |
|---|---|--|
| Light / minimum BFE & PFE protection | High BFE & PFE protection | High BFE & PFE protection |
| Used for general procedures and respiratory etiquette | More breathable than high barrier mask | |
| Designed to resist a splash or spray at venous pressure | Designed to resist a splash or spray at arterial pressure | Highest fluid resistance – designed to resist a splash or spray during tasks like orthopedic surgery or trauma |

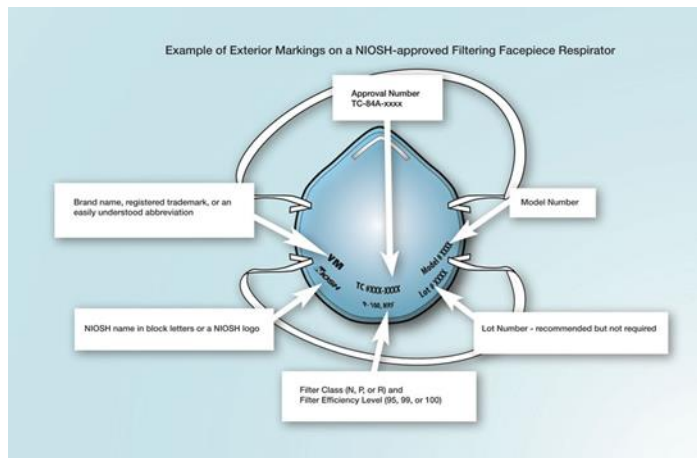
Table 3 - ASTM F2100-11 (2011) Requirements for medical face masks

| TEST | LEVEL 1 (LOW) BARRIER: 80 mm Hg | LEVEL 2 (MODERATE) BARRIER: 120 mm Hg | LEVEL 3 (HIGH) BARRIER: 160 mm Hg |
|---|--|--|--|
| BFE (Bacterial Filtration Efficiency) at 3.0 micron ASTM F2101 | ≥ 95% | ≥ 98% | ≥ 98% |

| | | | |
|---|---------|---------|---------|
| PFE (Particulate Filtration Efficiency) at 0.1 micron ASTM F2299 | ≥ 95% | ≥ 98% | ≥ 98% |
| Delta P (Differential Pressure) MIL-M-36954C, mm H ₂ O/cm ² | < 4.0 | < 5.0 | < 5.0 |
| Fluid Resistance to Synthetic Blood ASTM 1862, mm Hg | 80 | 120 | 160 |
| Flame Spread 16 CFR part 1610 | Class 1 | Class 1 | Class 1 |

Particulate Respirators:

- Respirators are personal protective equipment that tightly fit the face and filter airborne particles to protect health care workers.
- Particulate respirators are also known as “air-purifying respirators” as they protect by filtering particles (airborne biological agents such as bacteria or viruses are particles) out of the air as you breathe. These respirators protect only against particles—not gases or vapours.
- They provide a higher level of protection against viruses and bacteria when properly fit-tested. Achieving an adequate seal to the face is essential. In Sri Lanka, fit testing facility is not available in majority of the healthcare settings. But seal check should be performed at each time the respirator is used, without which the protection is not guaranteed.
- When properly fitted and worn, minimal leakage occurs around edges of the respirator when the user inhales. This means almost all of the air is directed through the filter.
- **NIOSH** (U.S. National Institute of Occupational Safety and Health) tests and certifies respirators based on their physical and performance characteristics, including filtration efficiency. For example, N95-rated filtering facepiece respirators (FFR) have a filtration efficiency of at least 95% against non-oily particles when tested using the NIOSH criteria (*table 1*).
- NIOSH-approved respirators have an approval label on or within the packaging of the respirator (i.e. on the box itself and/or within the users’ instructions) (*pictures 5*). Additionally, an abbreviated approval is on the FFR itself. You can verify the approval number on the NIOSH Certified Equipment List (CEL) or the NIOSH Trusted-Source page to determine if the respirator has been approved by NIOSH.



Picture 5 -NIOSH approved N95

- NIOSH-approved FFRs will always have one the following nine (9) designations: N95, N99, (European equivalent FFP2, FFP3) N100, R95, R99, R100, P95, P99, P100.
- Respirators that filter out at least 95% of airborne particles during “worse case” testing using a “most-penetrating” sized particle are given a 95 rating. Those that filter out at least 99% receive a “99” rating. And those that filter at least 99.97% (essentially 100%) receive a “100” rating.
- Respirators in this family are rated as N, R, or P for protection against oils. This rating is important in industry because some industrial oils can degrade the filter performance so it doesn’t filter properly. Respirators are rated “N,” if they are Not resistant to oil, “R” if somewhat Resistant to oil, and “P” if strongly resistant (oil Proof). Thus, there are nine types of disposable particulate respirators:

N-95, N-99, and N-100;
 R-95, R-99, and R-100;
 P-95, P-99, and P-100

- A surgical N95 (also referred as a medical respirator) is recommended only for use by healthcare personnel (HCP) who need protection from both airborne and fluid hazards (e.g., splashes, sprays).



Picture 6- Non-NIOSH respirator authorized by Umbrella EUA

- NIOSH evaluations show that many non-NIOSH approved international respiratory protective devices have inconsistent filtration performance and most assessments resulted in filtration **efficiencies less than 95%**. Apart from that here are many counterfeit “respirators” in the market, claimed to be NIOSH approved.
- Researchers at ECRI (medical device evaluating organization) found that up to 70% KN95 masks imported from China don’t meet U.S. standards for effectiveness as with N95 masks. The group issued a hazard warning in September. (Picture 7)

Signs that a respirator may be counterfeit:

- No markings at all on the filtering facepiece respirator (FFR)
- No approval (TC) number on filtering facepiece respirator or headband
- No NIOSH markings
- NIOSH spelled incorrectly
- Presence of decorative fabric or other decorative add-ons (e.g., sequins)
- Claims for the of approval for children (NIOSH does not approve any type of respiratory protection for children)
- Filtering facepiece respirator has ear loops instead of headbands



NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Fujian Yongtai Sanlian Garment Co., Ltd.
Model Tested: KN95
Date Tested: June 22, 2020

Picture 7- NIOSH not approved KN95

Only particulate filter efficiency was assessed.

On October 15, 2020, the FDA reissued the Emergency Use Authorization (EUA) for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China to revise the scope of authorization to authorize for emergency use only those respirators listed in the EUA's Appendix A as of the date of this reissuance. (*Picture 8*)



Picture 8- NIOSH not approved, FDA approved KN95

Reuse of Masks & respirators:

- Fabric masks can be reused after washing. Mask can be washed with tap water and laundry detergent or soap. Rinse thoroughly with clean water to remove detergent or soap. Dry properly & iron if possible, before reusing.
- Medical/Surgical masks are disposable. To safely discard your mask, place it in a plastic bag and put it in the trash. Wash your hands after handling the used mask.

- **Respirators:** In resource limited settings can practice extended use or reuse.
Extended use refers to the practice of wearing the same N95 respirator for repeated close contact encounters with several patients, without removing the respirator between patient encounters.
Reuse refers to the practice of using the same N95 respirator for multiple encounters with patients but removing it ('doffing') after each encounter. The respirator is stored in between encounters to be put on again ('donned') prior to the next encounter with a patient. NIOSH found that, as of April 2020, ultraviolet germicidal irradiation, vaporous hydrogen peroxide, and moist heat have shown the most promise as potential methods to decontaminate FFRs.
N95 FFR performance will decrease with decontaminations and as the number of hours and number of donnings and doffings increase.
The number of times that a FFR can be reused is limited by: fit, filtration performance, contamination and soiling or damage.

Summary:

Masks & respirators should be used as indicated. They should be used as part of a comprehensive strategy of measures (hand hygiene, physical distance respiratory etiquette) to suppress transmission and save lives; the use of a mask alone is not sufficient to provide an adequate level of protection against COVID-19.

The quality of masks & respirators available in Sri Lanka is questionable & it needs to be addressed centrally to avoid possible harm could be caused by false security given with poor quality personal protective equipment.

Furthermore, public awareness should be achieved on correct handling, donning & doffing strictly followed with proper hand hygiene before & after, for intended protection.