SASA
SOUTH AFRICAN SOCIETY OF ANAESTHESIOLOGISTS

SASA COVID-19 UPDATE

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N95/FFP2/3 RESPIRATOR MASKS & USAGE DURING COVID-19

Currently there is a global shortage of N95 and equivalent respirators with a massive influx of fraudulent or poorly manufactured and unregulated masks flooding the market, as well as an erratic supply of regulatory approved masks. This document is aimed at guiding members as to the end user basic assessment and utilisation of their respirators. The supply of these is non-uniform and mask design may vary greatly. This document will be updated as required and guided by the supply and manufacturing chain.

IMPORTANT POINTS TO NOTE:

- Covid-19 is transmitted in majority through respiratory droplet spread, transient respiratory aerosol spread, as well as trans-ocular and faeco-oral spread.
- In addition to rigorous and disciplined hand hygiene (WHO 5 moments of hand hygiene), appropriate usage, application and selection of Personal Protective Equipment (PPE) is vital.
- N95 or FFP2/3 respirator masks are currently recommended for protection against aerosolized viral particles.
- If respirators are not fitted, sealed and worn properly, as well as applied and removed appropriately, they do not assist in protecting the user from contracting Covid-19.
- There is currently insufficient evidence to conclusively state that any specific method of sterilisation of disposable respirators is reliably effective without compromising mask integrity and efficiency, or that any sterilisation method guarantees their impermeability to the virus post-sterilisation. For this reason, SASA can neither endorse nor support these methods, despite the critical shortage of masks nationally and internationally.
- Should sterilisation and re-use of disposable respirator masks be shown to be effective, safe and that the mask filtration capacity, durability and user functionality are not impaired by the sterilisation process, SASA will review these guidelines
- All respirators should be individually fit-tested to the user,and leak testing performed and confirmed with every application. Full fit testing is currently not feasible at every facility, but every mask ***must*** have leak testing performed prior to every use, with each donning process.
- If a mask is noted to be damaged or soiled in any way it should be immediately discarded.
- ***NB: Respirators cannot be worn safely and sealed appropriately if the user has a beard or facial hair***

Resource: SASA Recommendations on Personal Protective Equipment (PPE) for anaesthesia providers during the COVID-19 pandemic

RESPIRATOR TYPES/VARIANTS:

Respirators may be single use/disposable or re-usable.

1.Re-usable:

- Respirators must indicate that they have passed all fit tests and are at least N95 or equivalent for usage.
- Leak testing must be performed prior to every use, with each donning process.
- Re-usable respirators must consist of an adjustable strap/elastic attached to the moulded face piece in order to fix and fit to face.
- Mask scaffold may be re-usable and washable with a disposable filter.
- Filters may be fitted for use for a 8-12 hr shift only or in some cases, for up to 3 months as specified by each individual manufacturer and licensing approval.
- It is imperative to ensure that the cleaning instructions are meticulously followed for re-usable masks.
- Do not use the disposable filter beyond the period specified by manufacturer.
- Certain respirators are equipped with inhalation and exhalation valves.
- Inhalation valves must contain the appropriate viral filter so as to prevent inhaled air from potentially infecting the user.
- The NICD currently recommends the use of un-valved respirators.
- Because most valved respirators do not contain filters on the expiratory valve, the user may potentially infect the patient via droplet spread through this expiratory valve.
- Valved respirators could also unintentionally be used in a sterile field, resulting in the user potentially contaminating a sterile field via the unfiltered expiratory valve.
- Valves must be checked and approved to meet regulatory standards so as to not permit air from escaping beyond the valve filter limits into or out of the mask. If a valve is not within regulatory specification, the user may be at risk of being infected by entrained air.

2. Disposable:

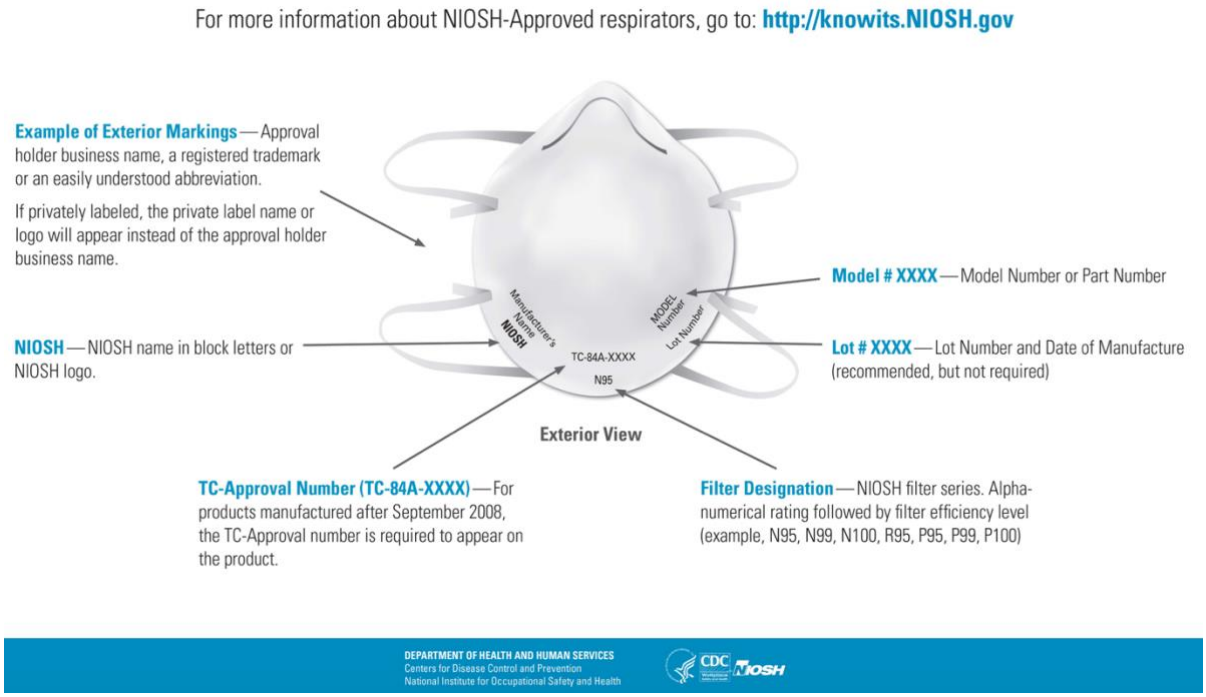
- These may be in the hard shelled cup or duck-bill soft form.
- These must consist of an adjustable strap/elastic attached to the moulded face piece in order to fix and fit to face.
- Currently no form of sterilisation is proven to be safe or effective for usage on these masks, as full permeability testing needs to be performed after each sterilisation to ensure regulatory approved viral filtration capability is maintained, and not only fit test and integrity of fabric.
- Exhalation valves may be present to aid in user comfort for respiration, but the NICD currently recommends the use of un-valved masks.

3.Modified Designs:

- All modified designs of full or half face masks must still be approved by SABS/NRCS and SAPHRA as respirators are required to be registered as Class B devices.
- Filtration material used must indicate regulatory approval to be equivalent to N95/FFP2 minimum filtration designation.
- Please note that some products are labelled as approved or as N95/FFP2, but are, in fact, fraudulent. It is essential to check that the supplier, and their product, has been appropriately vetted and fit testing, leak testing and regulatory documentation of these tests must be available https://www.nrcs.org.za/news.asp?upd=1&newsID=4144.
- Improperly fitted masks can result in infection with Covid-19 or respiratory compromise of the user with prolonged usage.
- Modification of masks that includes usage of ancillary pieces of equipment mandates that the ancillary equipment be certified as appropriate and safe specifically for usage in this off label manner. This includes the use of HEPA and HME filters outside of closed ventilator circuits.
- Without appropriate independent regulatory approval and certification of the entire mask as a unit, the mask's safety and functionality cannot be guaranteed.
- The filter must be checked for durability and safety in the context of its off label usage as it may not be a fit for purpose design for respirators.
- Because NICD ideally recommends the usage of un-valved masks and, specifically where a mask has been modified or prototype engineered to include a valved system, there must be appropriate accompanying testing evidence that this valve meets all regulatory specifications.

RESPIRATOR LABELLING:

- Please carefully check for the regulatory markings, manufacturer detail and filter designation as labelled below.
- N95, KN95, FFP2, FFP3 are all appropriate respirator filtration levels for Covid-19.



APPLICATION OF MASK:

- Ensure hands are thoroughly washed as per guidelines (WHO 5 moments of hand hygiene).
- Avoid touching the inside/facial surface of the mask at all times.
- To place the mask on the face , the user must ensure that the mask is held in a cupped palm with the anterior/external aspect of the mask facing palm-down.
- For duck-billed masks first use the thumb and forefinger to carefully open the edges of the mask and stretch apart.
- Masks must then be placed over the nose and chin, with malleable wire rim over nasal bridge where present (ideally an image of this fit should be provided by the manufacturer, especially with respect to reusable masks).
- Elastics must not be crossed over the back of the head, bottom elastic must sit underneath ears and wrap around the base of skull and top elastic must sit above ears and wrap around the occiput.
- If a malleable wire rim is present, this must then be firmly moulded to fit snugly over and around the nasal bridge so the mask is applied directly against the skin.

- Once fit and leak testing is completed, move to the donning and doffing area and proceed to don the mask as per protocol (SASA COVID-19 Donning Video).

FIT TESTING:

- All respirators must have undergone full fit testing locally or internationally as per regulatory standards for approval.
- Currently it is not possible to do full fit testing for every end user. Ensure that the manufacturer can provide evidence that this has been done and the necessary tests passed according to specification.
- Without appropriate and acceptable fit testing, the permeability, seal preservation, material fit to face, durability, as well as filtration of viral molecules cannot be guaranteed.
- User tolerance of increased respiratory effort needs to be confirmed as these masks increase resistance to breathing to varying degrees depending on specific design, filter material and the presence or absence of valves.
- Users with underlying pulmonary hypertension, underlying significant respiratory disease or severe claustrophobia may not tolerate the usage of respirator masks and are therefore cautioned to test their personal level of tolerance with mild exercise prior to entering their contaminated or infected place of work.
- Although specific filtration for viral particles cannot be formally tested for by the end user, a basic screening for this can include inhaling through the mask in the presence of a plume of talc powder. This plume includes particles within their lower size range that approach 0,4 microns in size, which is analogous to those of Covid-19 viral molecules. If the user is able to smell talc powder through the mask, then filtration or seal is not considered optimal and will not enable 95% or higher protection against infection.

LEAK TESTING:

- All masks, reusable/disposable/modified, must be applied to the face and tested for leaks on inspiration and expiration by the user each time they are used.
- Because there is significant variation in current available stock, users should not rely on the size labelling of the mask as a reliable indicator that the mask will fit uniformly.
- In order to fit correctly and not allow for leaks, masks are generally noted to feel tight over the face and nasal bridge and often somewhat uncomfortable, especially with prolonged usage.
- Both inspiratory and expiratory leak tests must be performed and these must be repeated with the head in the following positions:
    1. Neutral position
    2. Neck in full extension
    3. Neck in full flexion
    4. Head turned to both left and then right side
    5. Grimacing expression

- In order to check for inspiratory leaks, follow the steps below:
    1. If the mask contains an inspiratory valve, place palm of hand firmly over valve, alternatively in unvalved masks ensure fit is appropriate prior to testing
    2. Take a rapid deep breath in, whilst keeping your hand firmly over the valve.
    3. Masks should pull into the face firmly but no air should entrain under the chin, via the sides at cheeks, or over the nasal bridge.
    4. Negative pressure generated should enable softer masks to tighten and pull inwards slightly against the face without inverting or collapsing.
    5. If any air is felt to entrain, attempt to refit or reposition the mask using tightening of straps, or pinching and adjustment of nasal bridge area and repeat tests.
- In order to check for expiratory leaks, follow the steps below:
    1. If the mask contains an expiratory valve, place the palm of hand firmly over the valve, alternatively in unvalved masks ensure fit is appropriate prior to testing.
    2. Forcefully and rapidly exhale, whilst keeping the palm of hand firmly over the valve.
    3. Positive pressure generated should enable slight filling outwards of softer masks without lifting off face.
    4. If any air is felt to escape outwards under the chin, out the sides at cheeks, or specifically up over the nasal bridge, attempt to refit or reposition the mask as above and repeat tests.

REMOVAL OF MASK:

- This must form part of standard doffing protocol after exposure to contaminated area or infected patient/PUI. (SASA COVID-19 Doffing Video).
- Untie or grasp the fastening straps at back of head and pull forwards over forehead.
- Do not at any stage touch the exterior-facing aspect of the mask as this is contaminated.
- Ideally do not touch or handle interior-facing aspect of mask either, and grasp only the fastening straps.
- If re-usable, follow the cleaning regimen as part of doffing protocol and manufacturer instructions.
- If disposable, discard in an appropriate biohazard waste bin.
- Complete doffing protocol as directed.

Understanding the Difference

	 Surgical Mask	 N95 Respirator
Testing and Approval	Cleared by the U.S. Food and Drug Administration (**FDA**)	Evaluated, tested, and approved by **NIOSH** as per the requirements in 42 CFR Part 84
Intended Use and Purpose	Fluid resistant and provides the wearer protection against large droplets, splashes, or sprays of bodily or other hazardous fluids. Protects the patient from the wearer's respiratory emissions.	Reduces wearer's exposure to particles including small particle aerosols and large droplets (**only non-oil aerosols**).
Face Seal Fit	Loose-fitting	Tight-fitting
Fit Testing Requirement	No	Yes
User Seal Check Requirement	No	Yes. Required each time the respirator is donned (put on)
Filtration	Does NOT provide the wearer with a reliable level of protection from inhaling smaller airborne particles and is not considered respiratory protection	Filters out at least 95% of airborne particles including large and small particles
Leakage	Leakage occurs around the edge of the mask when user inhales	When properly fitted and donned, minimal leakage occurs around edges of the respirator when user inhales
Use Limitations	Disposable. Discard after each patient encounter.	Ideally should be discarded after each patient encounter and after aerosol-generating procedures. It should also be discarded when it becomes damaged or deformed; no longer forms an effective seal to the face; becomes wet or visibly dirty; breathing becomes difficult; or if it becomes contaminated with blood, respiratory or nasal secretions, or other bodily fluids from patients.

Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health