SASA SOUTH AFRICAN SOCIETY OF ANAESTHESIOLOGISTS

SASA COVID-19 UPDATE

Issued 15 June 2020, 15h00

N95/EQUIVALENT RESPIRATOR QUALITY SCREENING GUIDE

SASA is aware of fraudulent, poor quality, substandard or unapproved respirators that are being distributed, donated, procured or sold to facilities, clinicians and frontline workers nationally. We are continuing to engage with all relevant parties involved in these processes to try to ensure that what you receive will protect and provide the necessary functional requirements required by a respirator during the pandemic. Because there are many role players and steps in the process of procurement and regulatory vetting and approval, we have endeavored to provide you with a basic screening template against which you can crosscheck your respirator prior to donning it. This unfortunately does not protect against those companies that have fraudulently printed the appropriate standards or provided counterfeit regulatory certificates, but it does at least enable you to know what the minimum requirements should be. This document focuses on the disposable half-face respirator as these are currently the most commonly supplied version in our settings. Remember to also thoroughly inspect the respirator itself to ensure that it is not physically damaged or soiled prior to usage. Please inform the SASA Covid-19 Working Group if you encounter any issues or concerns related to your respirators.

Basic Regulatory Information:

1. Packaging:
   - Storage box should not be damaged or exhibit signs of any mould.
   - Manufacturer details should be clear, including the manufacturer address.
   - Grade of respirator and volume contained should be clearly marked (FFP2, FFP3, N95, KN95).
   - GB, EN or SABS registration standard *must be* printed clearly on the packaging.
   - CE stamp should be clear, if approved.
   - If locally made, CE and FDA approval may not yet be complete but SABS and/ NCRS, as well as SAPHRA standards and criteria for approval must be met.
   - Pending approval for SAPHRA is not acceptable as this may imply that appropriate testing processes have not been completed or full permeability testing passed at appropriate minimum regulatory levels.
   - Batch/Lot number must be clearly marked.
   - There should be no spelling mistakes or font errors in standard fonts e.g.: CE mark, EN regulation etc.

2. Respirator:
   - All respirators should ideally be stamped or marked to indicate regulatory standards and registration, "no-name brands" may be appropriate for usage but then the regulatory certification ***must*** be checked and verified to ensure that the respirator is compliant.
   - See the below diagram for examples of marking sites.
   - Markings and regulatory criteria differ depending on the type of respirator, but the majority of respirators supplied are disposable half face respirators.
   - Each mask must be adjustable and have a mechanism by which to adjust the fit over the nasal bridge, and tighten the mask around the face so as to create a proper seal.
   - Respirators with ear-loops are often more difficult to appropriately adjust to seal or fit tightly and comfortably. If ear-loops are present but the rest of the respirator is compliant, ensure that either the ear-loops are fully adjustable in order to ensure proper seal and fit, or that a clip for the ear-loops is provided so as to ensure adjustability (see image below).
   - The nasal bridge portion of the respirator must have an adjustable/malleable portion by which the respirator can be moulded to fit the user's nasal bridge.
   - See SASA's Guidelines on fit and leak testing. Click here
   - Respirator efficiency is dependent on and linked to appropriate room ventilation in the environment in which it is used, and the duration of the exposure. Ensure that the environment in which you share contact with patients is appropriately ventilated (minimum 12 air changes per hour – equivalent to a room with windows and doors open).

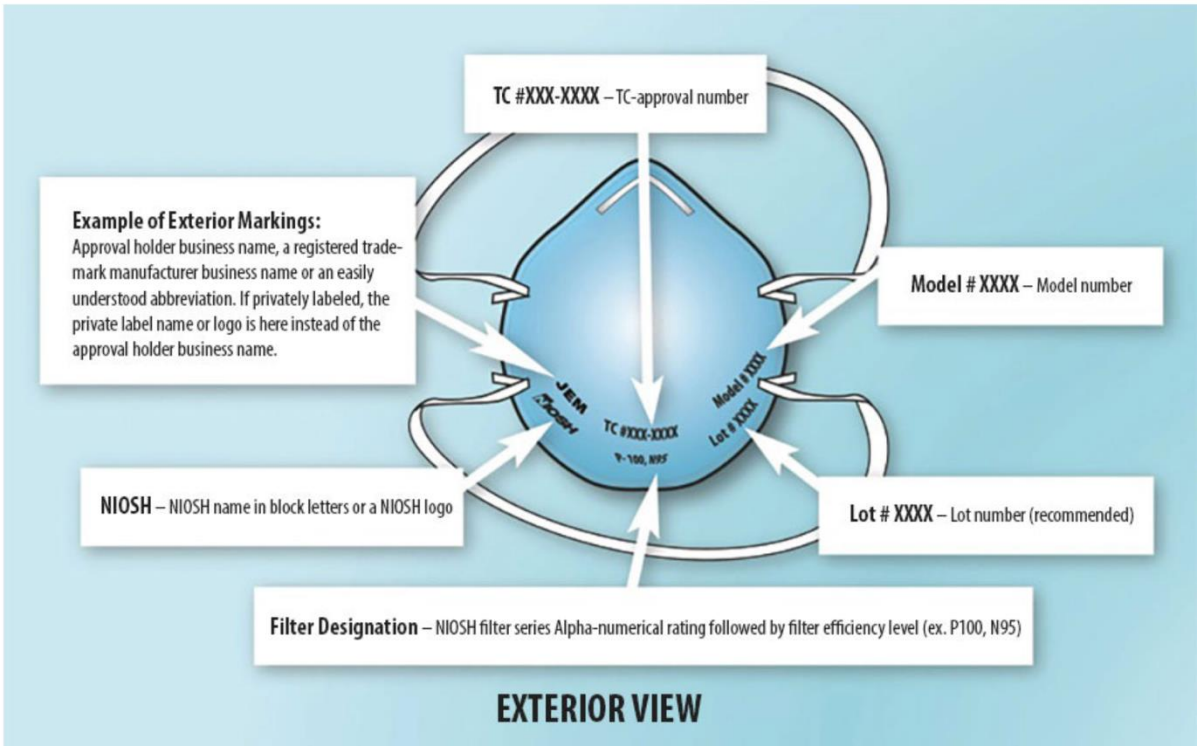
3. Regulatory standards for half face disposable respirator:
   - EN 149:2001 is the minimum standard for the half-face disposable respirators that can be safely used during the pandemic for AGP's.
   - GB 2626-2019 or GB 19083:2010 are the updated Chinese standards applicable for KN95 respirators.
   - N95, FFP2, FFP3, KN95 are all currently accepted respirator grades.
   - Filtration must therefore meet a minimum of 94% particle filtration, as well as meeting a number of additional safety and permeability tests (see table below).
   - Respirator must not have exceeded its shelf life as beyond this date, none of the tests below, as well as the structural integrity can be guaranteed, and permeability specifically is often impaired.
   - If FDA approved, the NIOSH website will provide the required procedure standards, testing and protocols the respirator must meet, as well as advise as to whether the respirator is indeed approved as it will be listed on their website - https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/default.html
   - If previously approved, but no longer verified due to standards or quality violations, it can be found on the below link - https://www.fda.gov/media/137928/download

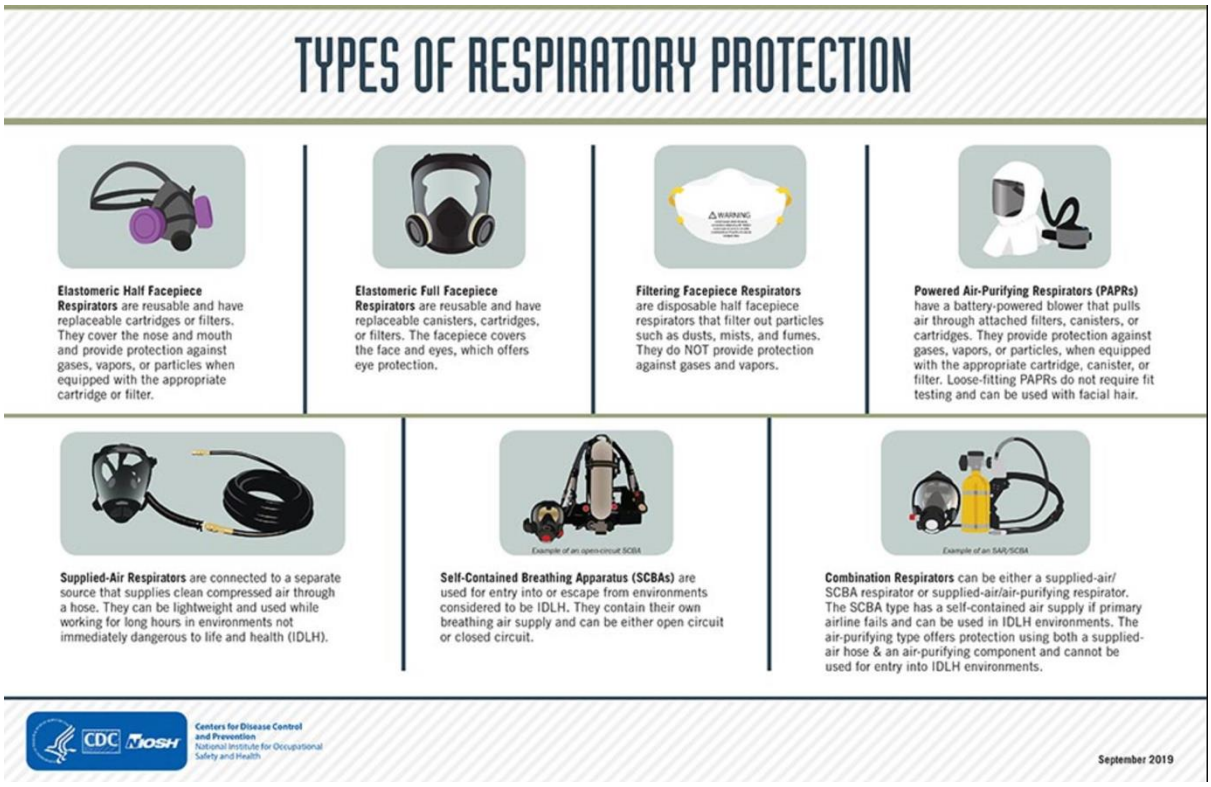
Examples of ear-loop clips in order to adjust respirator:





Sample of a generic filtering facepiece respirator with appropriate markings.





3M Personal Safety Division

Definitions

Filter performance – the filter is evaluated to measure the reduction in concentrations of specific aerosols in air that passes through the filter.

Test agent - the aerosol that is generated during the filter performance test.

Total inward leakage (TIL) – the amount of a specific aerosol that enters the tested respirator facepiece via both filter penetration and faceseal leakage, while a wearer performs a series of exercises in a test chamber.

Inward leakage (IL)– the amount of a specific aerosol that enters the tested respirator facepiece, while a wearer performs a normal breathing for 3 minutes in a test chamber. The test aerosol size (count median diameter) is about 0.5 micro meter.

Pressure drop – the resistance air is subjected to as it moves through a medium, such as a respirator filter.

IMPORTANT: Always read and follow respirator user instructions.

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Based on this comparison, it is reasonable to consider China KN95, AS/NZ P2, Korea 1st Class, and Japan DS2 FFRs as "similar" to US NIOSH N95 and European FFP2 respirators, for filtering non-oil-based particles such as those resulting from wildfires, PM 2.5 air pollution, volcanic eruptions, or bioaerosols (e.g. viruses). However, prior to selecting a respirator, users should consult their local respiratory protection regulations and requirements or check with their local public health authorities for selection guidance.

Certification/ Class (Standard)	N95 (NIOSH-42C FR84)	FFP2 (EN 149-2001)	KN95 (GB2626-2006)	P2 (AS/NZ 1716:2012)	Korea 1st Class (KMOEL - 2017-64)	DS2 (Japan JMHLW-Notification 214, 2018)
Filter performance – (must be ≥ X% efficient)	≥ 95%	≥ 94%	≥ 95%	≥ 94%	≥ 94%	≥ 95%
Test agent	NaCl	NaCl and paraffin oil	NaCl	NaCl	NaCl and paraffin oil	NaCl
Flow rate	85 L/min	95 L/min	85 L/min	95 L/min	95 L/min	85 L/min
Total inward leakage (TIL)* – tested on human subjects each performing exercises	N/A	≤ 8% leakage (arithmetic mean)	≤ 8% leakage (arithmetic mean)	≤ 8% leakage (individual and arithmetic mean)	≤ 8% leakage (arithmetic mean)	Inward Leakage measured and included in User Instructions
Inhalation resistance – max pressure drop	≤ 343 Pa	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min) ≤ 500 Pa (clogging)	≤ 350 Pa	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)
Flow rate	85 L/min	Varied – see above	85 L/min	Varied – see above	Varied – see above	40 L/min
Exhalation resistance - max pressure drop	≤ 245 Pa	≤ 300 Pa	≤ 250 Pa	≤ 120 Pa	≤ 300 Pa	≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)
Flow rate	85 L/min	160 L/min	85 L/min	85 L/min	160 L/min	40 L/min
Exhalation valve leakage requirement	Leak rate ≤ 30 mL/min	N/A	Depressurization to 0 Pa ≥ 20 sec	Leak rate ≤ 30 mL/min	visual inspection after 300 L /min for 30 sec	Depressurization to 0 Pa ≥ 15 sec
Force applied	-245 Pa	N/A	-1180 Pa	-250 Pa	N/A	-1,470 Pa
CO_2 clearance requirement	N/A	≤ 1%	≤ 1%	≤ 1%	≤ 1%	≤ 1%

*Japan JMHLW-Notification 214 requires an Inward Leakage test rather than a TIL test.