

Rapid evidence checks are based on a simplified review method and may not be entirely exhaustive, but aim to provide a balanced assessment of what is already known about a specific problem or issue. This brief has not been peer-reviewed and should not be a substitute for individual clinical judgement, nor is it an endorsed position of NSW Health.

Respirator fit testing

Rapid review question

What is the effectiveness of fit testing (both qualitative and quantitative methods) and fit checking for testing the protection of a respirator and what are the factors influencing the outcomes of fit testing?

What are the differences in outcomes between the qualitative and quantitative fit testing methods?

In brief

The purpose of fit testing is to ensure that the selected make, model and size of a respirator issued to a wearer forms an adequate seal around the wearer's face and provides the intended level of protection.(1) The Australian New Zealand Standard AS/NZS1715:2009 *Selection, Use and Maintenance of Respiratory Protective Equipment* states that fit testing can be performed using qualitative or quantitative methods.(2)

- Qualitative fit testing is a pass/fail test method that uses the wearer's sense of taste or smell to detect leakage into the respirator facepiece. This type of fit testing is usually used for half-mask respirators.(3)
- Quantitative fit testing measures the amount of leakage into the facepiece using a generated aerosol, ambient aerosol or controlled negative pressure. This type of fit testing connects a respirator to a machine using a probe attached to the respirator.(3)

Fit checking (user-seal check) describes the process that health workers perform each time a respirator is donned to check that a good facial seal is achieved, i.e. the respirator is sealed over the bridge of the nose and mouth and there are no gaps between the respirator and the face.(4)

Qualitative fit testing method

- In a clustered randomised study, there was no significant difference in the respiratory tract infection rate between the qualitatively fit-tested and not-fit-tested N95 respirator groups.(5) N95 respirator groups had half the rate of infection compared to medical mask groups.(5) One study found that N95 respirators, despite passing the qualitative fit testing on subjects, failed to block the aerosolised live attenuated influenza vaccine strains in 10% of the cases during a 20 minute exercise session in a test chamber.(6)

- Qualitative fit testing result has been shown to be affected by training healthcare workers on the correct use of respirators,(7, 8) the testing agent (Bitrex versus saccharin),(9) gender,(10) and applying skin protectants.(11)

Quantitative fit testing method

- Four studies found that the fit factor obtained from quantitative fit testing may decrease when performing simulated medical procedures, such as chest compressions,(12, 13) nursing procedures(14) and endotracheal intubation.(15) In other studies, passing the quantitative fit test resulted in increased rates of an adequate level of simulated workplace protection.(16, 17)
- Quantitative fit testing results have shown to be affected by: training healthcare workers to correctly use respirators,(18) tester prior experience with fit testing,(19) tester assistance with donning and doffing of respirators,(20) wearers' race and facial characteristics,(19, 21, 22) subsequent donning,(23) wearer's weight change over time,(24) facial hair(25, 26) and types of respirators (fold-type versus cup or valve-type).(13, 15, 18)

Qualitative versus quantitative fit testing methods

- Six studies tested respirators both qualitatively and quantitatively on the same subjects.
 - The pass-fail rates of the two methods varied across studies. In three studies, qualitative fit testing resulted in lower pass rates and higher failure rates than quantitative fit testing.(27-29), while in the other two studies, qualitative fit testing had a higher pass rate and a lower failure rate.(30, 31) In the sixth study, the differences in the pass-fail rates between the quantitative and qualitative methods were found to be dependent on the model of the respirator being tested.(32)
 - In one of these studies, subjects who passed either the qualitative or quantitative fit testing had a higher level of protection (determined by measuring filter penetration and face seal leakage) when compared to before being fitted and those who failed the tests.(29)
- Two studies measured the errors associated with fit testing methods. The first study found qualitative fit testing was more likely to fail a subject whose respirator provided adequate protection quantitative fit testing.(33) A respirator was considered to provide adequate protection if the 5th percentile simulated workplace protection factor, which is a measure of the protection a subject received from a respirator in a simulated workplace environment, was ≥ 10 .(33, 34) The second study found the opposite results, with the qualitative fit testing method with Bitrex least likely to fail a respirator that provided adequate protection.(34) In the second study, quantitative fit testing was found to less likely to pass respirators that provided less than expected level of protection.(34)
- Physiological effects of fit testing methods were measured in one study. It found that qualitative fit testing may cause physiological discomfort due to elevated CO₂ level and decreased O₂ level inside the respirators when test hoods are used.(35) During quantitative fit testing, O₂ levels inside the respirators also dropped, although not as significant as when qualitative fit testing was conducted.(35)

Fit checking versus fit testing

- Australian COVID-19 guidance is consistent in advising that fit checking of masks should be applied.

- Studies generally found that although user seal checking was not as sensitive as fit testing in identifying leakage, appropriate training on performing fit checking could improve the overall fit performance of the respirators.(36)

Limitations

There are variations in the models of respirators being tested, equipment used for the testing and the procedures undertaken during the testing across included studies. Studies were included from 2000 to present. The models of respirators and devices used for testing may not be representative of those commonly being used in current healthcare settings.

Background

Fit testing is useful in identifying an appropriate respirator that accommodates an individual's facial characteristics which is more likely to provide adequate protection for that individual.(1) Passing the fit test with a certain respirator does not guarantee satisfactory fit every time when the respirator is worn.(1) User fit checking each time when donning a respirator is recommended.(1, 4)

The Clinical Excellence Commission released a resource in October 2020 on 'Respiratory Protection Program Implementation Resources'. This resource describes training, risk assessment and management, types of respiratory protective equipment, fit checking and fit testing.(54) This and previous CEC guidance suggest a risk-management approach to identifying and prioritising healthcare workers for fit testing, which takes into account factors such as healthcare workers who regularly work in areas with significant risk of exposure to disease and who perform or assist in aerosol generating procedures (AGPs).(4, 54) Australian Department of Health: Guidance on the minimum recommendations for the use of personal protective equipment (PPE) in hospitals during COVID-19 outbreak recommends that particulate filter respirators, such as P2/N95 respirators, to be used in the context of AGPs or aerosol generating behaviours (AGBs) and other specified circumstances which require contact and airborne precautions.(55)

- Fit testing is a validated method for matching particulate filter respirators (PFRs) with an individual's facial shape, but has not been widely applied in Australia.
- Despite increased awareness and demand, in the context of COVID-19, it is acknowledged that fit testing of all health care workers who may need to use a particulate filter respirator, will be difficult to accomplish due to limited supplies and range of types/sizes available.
- It is noted that fit-testing does not guarantee that a respirator will not leak and reinforces the need to fit-check with each use.

Fit testing can be time and resource intensive, especially during a major public health crisis and when there is a shortage of filtering facepiece respirators.(37) Different types of masks included in this review are generally traditional in design. There is an opportunity for innovation in the design of masks, including assessment on whether the current design of masks is optimal.

Methods (Appendix 1)

PubMed and Google searches were conducted on 26 August 2020. Only peer-reviewed literature was included.

Results

Table 1: Qualitative fit testing

Source	Advice
Peer-reviewed sources	
<p>A pilot study of the impact of facial skin protectants on qualitative fit testing of N95 masks</p> <p>Bui, et al. 2020 (11)</p>	<ul style="list-style-type: none"> • Subjects: 25 employees of two health facilities who had previously been fit tested. • Test: Qualitative fit testing. • Respirator: N95 mask (3M 1860). • Procedure: Subjects each underwent five qualitative fit testings after self-applying five types of skin protectants, e.g. DuoDerm, Mepitec tape or similar. • Results: <ul style="list-style-type: none"> ○ Nine (36.0%) participants passed the qualitative fit test with all five types of skin protectants. The pass rates for qualitative fit testing with different skin protectants ranged from 56.0% to 88.0%. • Conclusion: Use of skin protectants with N95 respirators may interfere with the fit performance of the respirator, particularly on movement.
<p>Assessment of the qualitative fit test and quantitative single-pass filtration efficiency of disposable N95 masks following Gamma Irradiation</p> <p>Gramer, et al. 2020 (38)</p>	<ul style="list-style-type: none"> • Respirators: 3M 8210, 3M 1805 and 3M 9105. • Procedure: Respirator masks were subjected to different doses of Gamma irradiation of 0kGy, 1kGy, 10kGy and 50kGy. One mask with no (0kGy) irradiation and three masks with three different doses of irradiation from each mask type underwent qualitative fit testing. The remaining masks were tested for particulate single-pass filtration efficiency with three different particle sizes (0.3, 0.5 and 11µm). • Results: <ul style="list-style-type: none"> ○ All nine masks with different doses of irradiation passed qualitative fit testing. ○ Compared to masks that received no (0kGy) irradiation, all irradiated masks had a significant reduction in their single-pass filtration efficiency, regardless of the dose of irradiation, mask type and particle size. • Conclusion: Qualitative fit tests may not be adequate in assessing the integrity of masks. Sterilising masks using Gamma radiation degrades the filtration efficiency of masks.

Source	Advice
Peer-reviewed sources	
	<ul style="list-style-type: none"> This study has limitations. The test that was used to assess filtration efficiency is not approved by the National Institute for Occupational Safety and Health, and particulate matter smaller than 0.3µm was not examined.
<p>How well do N95 respirators protect healthcare providers against aerosolised influenza virus?</p> <p>Bischoff, et al. 2018(6)</p>	<ul style="list-style-type: none"> Subjects: 58 employees of a medical school. Tests: Qualitative fit testing. Respirator: Kimberly-Clark N95 particulate filter respirator and novel half-mask powered air-purifying respirator. Procedure: Subjects were randomised into two groups, each wearing either the N95 respirator or the powered air-purifying respirator. Subjects underwent and passed the qualitative fit testing and then were exposed to aerosolised live attenuated influenza vaccine strains in a test chamber for 20mins. Nasal swabs were taken from the subjects after the exposure. Results: <ul style="list-style-type: none"> In the N95 respirator group, influenza virus was detected in three (10%) of subjects after the exposure. In the powered air-purifying respirator group, influenza virus was not detected in any subjects. Conclusion: N95 respirators which passed the qualitative fit tests on subjects may still fail to block the influenza virus in 10% of cases.
<p>The education and practice program for medical students with quantitative and qualitative fit test for respiratory protective equipment</p> <p>Myong, et al. 2016 (8)</p>	<ul style="list-style-type: none"> Subjects: 50 senior medical students. Test: Qualitative fit testing (saccharin solution). Respirators: VFlex 9102S and VFlex 9102. Procedure: Subjects participated in an education program on selection and use of personal protective equipment, performing fit checks and fit tests. Subjects completed qualitative fit testing using a chosen respirator before and after the education program. Results: <ul style="list-style-type: none"> The pass rate for qualitative fit testing significantly increased from 30% at baseline to 74% after the education program. Those who changed from medium-size respirator at baseline to small-size after the education program significantly increased the pass rate (p<0.001).

Source	Advice
Peer-reviewed sources	
<p>A Cluster Randomized Clinical Trial Comparing Fit-Tested and Non-Fit-Tested N95 Respirators to Medical Masks to Prevent Respiratory Virus Infection in Health Care Workers</p> <p>MacIntyre, et al. 2011 (5)</p>	<ul style="list-style-type: none"> • Conclusion: Providing training on fit checking and fit testing and proper use of personal protective equipment can increase the fit performance of the respirators. • Subjects: 1441 healthcare workers in 15 hospitals in Beijing, China. • Tests: Qualitative fit testing (Bitrex). • Masks: Medical mask (3M 1820), fit-tested N95 respirator (3M flat-fold 9132) and non-fit-tested N95 respirator (3M flat-fold 9132). • Procedure: Subjects were cluster randomised into three mask groups. Subjects wore assigned masks or respirators during work shifts for a four-week period. Outcome measures were compared with a convenience sample of 481 healthcare workers who wore no masks. • Outcome measures: Clinical respiratory illness, influenza-like illness, laboratory-confirmed respiratory virus infection and influenza. • Results: <ul style="list-style-type: none"> ○ five (1.08%) subjects who were fit tested failed the qualitative fit test, yielding a very low failure rate. ○ The rates of all outcomes for the medical mask group and N95 respirator groups were 3.9% vs 6.7% for clinical respiratory illness, 0.3% vs 0.6% for influenza-like illness, 1.4% vs 2.6% for laboratory-confirmed respiratory virus and 0.3% vs 1% for influenza. ○ There was no significant difference in outcomes between the fit-tested and non-fit-tested N95 respirator groups. ○ By intention-to-treat analysis, when p values were adjusted for clustering, there was a significant difference in the rates of clinical respiratory illness between the non-fit-tested N95 respirator group and the medical mask group (p=0.045). No significant differences were found in outcomes between the fit-tested N95 respirator group and the medical mask group. Compared to the no-mask group, only the N95 respirator group had significantly lower rates of infection. • Conclusions: Medical mask group had double the risk of infection compared to the N95 respirator group, suggesting the benefits of using respirators. The fit test finding is specific to the model tested and may not be transferrable to other models.

Source	Advice
Peer-reviewed sources	
<p>Particulate face masks for protection against airborne pathogens - one size does not fit all: an observational study</p> <p>Winter, et al. 2010 (7)</p>	<ul style="list-style-type: none"> • Subject: 50 volunteer hospital staff from a general intensive care unit from Australia, who had no facial hair and were not pregnant. • Test: Qualitative fit testing with either the Bitrex or saccharin solution, depending on the subject's sensitivity test results. • Respirators: Kimberly-Clark Tecnol FluidShield N95 particulate filter respirator (KC), 3M Flat Fold 9320 particulate respirator and 3M 8822 particulate respirator with exhalation valve. • Procedure: Each subject completed fit testing with each of the three types of respirators in random order. If a subject failed the fit testing, a training (posters and DVDs provided by the manufacturers) on correct fitting was provided, and the fit test for that respirator was repeated afterwards. • Main outcome measures: pass rate for the fit test for each respirator model and predictors of fit test results. • Results: <ul style="list-style-type: none"> ○ Pass rates before the provision of any training: 16% for KC, 28% for 3M flat fold, and 34% for 3M valved. ○ Pass rates improved significantly after the training: 28% for KC, 48% for 3M flat fold, 54% for 3M valved. ○ 28% of subjects failed to pass fit tests with any of the respirators, even after the training. ○ No factors, including sex, age, head circumference, occupation and order of respirator testing, were found to predict the fit test results. • Conclusion: Provision of training on the correct fitting of respirators could improve the fitting outcomes. Hospitals are recommended to provide a variety of respirators for staff to be fitted with, as pass rates across respirators varied and around 1 in 4 staff failed to obtain a pass with any of the three given respirators.
<p>Implementing fit testing for N95 filtering facepiece respirators: Practical information from a large cohort of hospital workers</p>	<ul style="list-style-type: none"> • Subjects: 1271 healthcare workers. • Test: Qualitative fit testing (Britex) • Respirators: N95 particulate respirator models (3M 1870, 3M 1860s or 3M 8210), N95 particulate respirator model (Moldex-Metric 2200N) and Respir-X model SAP5200

Source	Advice
Peer-reviewed sources	
McMahon, et al. 2008 (10)	<ul style="list-style-type: none"> • Procedure: Subjects first tested with the 3M 1870 model and went on to test with other models if they failed the test. • Results: <ul style="list-style-type: none"> ○ The pass rate for the first-tested respirator (3M 1870) was 95.1% for men and 85.4% for women (P<0.01). ○ Six women did not pass the qualitative fit testing with any of the provided respirators. • Conclusion: Men had a higher pass rate than women.
<p>Capability of Respirator Wearers to Detect Aerosolized Qualitative Fit Test Agents (Sweetener and Bitrex) with Known Fixed Leaks</p> <p>McKay and Davies, 2000 (9)</p>	<ul style="list-style-type: none"> • Subjects: 26 subjects. • Tests: Qualitative fit testing (saccharin and Bitrex). • Respirators: Moldex 8000 half-face elastomeric respirators with known fixed leaks. • Results: <ul style="list-style-type: none"> ○ The mean fit factor for respirators was 67 ± 29 SD (tested using PortaCount model 8010; recommended fit factor 100). ○ Nine (35%) subjects were not able to sense the saccharin solutions. All subjects were able to sense the Bitrex solution. • Conclusion: Saccharin solution is inferior to Bitrex solution in detecting leaks during qualitative fit testing. Masks with leaks may pass qualitative fit testing when saccharin solution was used despite not passing the quantitative fit testing.

Table 2: Quantitative fit testing

Source	Summary
Peer reviewed sources	
<p>A close shave? Performance of P2/N95 respirators in healthcare workers with facial hair: results of the BEARDS (BENchmarking Adequate Respiratory DefenceS) study</p> <p>Sandaradura, et al. 2020 (26)</p>	<ul style="list-style-type: none"> • Subjects: 105 healthcare workers from Sydney, Australia. • Test: Quantitative fit testing (PortaCount Pro+ 8038). • Respirator: 3M Flatfold 1870 filtering half-facepiece respirator. • Procedure: Subjects’ facial hair was categorised by two investigators by examining their facial photographs. Subjects performed user seal checks and investigators performed visual checks before fit testing. • Results: <ul style="list-style-type: none"> ○ Of 38 clean-shaven men, 18 (47%) passed the fit test. ○ Of 20 men with light stubble, 8 (40%) passed the fit test. ○ Of 21 men with heavy stubble, 6 (29%) passed the fit test. ○ Of 20 men with a full beard, none (0%) passed the fit test. ○ Only 3 out of 71 (4%) fails of the fit test were identified by user seal checks • Conclusion: Males with full beards are unlikely to achieve an adequate facial seal with disposable respirators. Adequate respirator fit decreased significantly with increasing facial hair.
<p>Quantitative fit testing with limited supplies of respirator masks in hospital personnel during the COVID-19 pandemic</p> <p>Cameron, et al. 2020 (39)</p>	<ul style="list-style-type: none"> • Subjects: 371 medical, nursing and allied healthcare workers from Sydney, NSW. • Test: Quantitative fit testing (PortaCount Pro+ 8038). • Respirators: N95 respirator masks (3M 1860 and 1860S, ProShield TN01–11 and TN01–12). • Results: <ul style="list-style-type: none"> ○ 23 (6.2%) failed the quantitative fit testing with all four types of masks. ○ Those who failed were further tested with 3M Aura 1870+ mask and six (1.6% of all subjects) failed the test. • Conclusion: The overall failure rate for the quantitative fit test with commonly used masks in Australia is small, although there are variations between different types of masks.
<p>Selection and Use of Respiratory Protection by Healthcare Workers to Protect from Infectious Diseases in Hospital Settings</p>	<ul style="list-style-type: none"> • Subjects: 20 healthcare workers from Sydney, Australia. • Test: Quantitative fit testing. • Respirator: CleanSpace2™ powered air-purifying respirators (PAPRs).

Source	Summary
Peer reviewed sources	
<p>Chughtai, et al. 2020 (40)</p>	<ul style="list-style-type: none"> • Procedure: Subjects were interviewed about their views and attitudes towards selection and use of face masks and respirators in hospitals. They then underwent quantitative fit testing. • Results: <ul style="list-style-type: none"> ○ All participants passed quantitative fit testing with a single test. ○ The exit survey revealed that 14 (70%) and 15 (75%) subjects rated PAPRs easy to don and doff, respectively. On a scale from one (very bad) to nine (very good), all participants rated PAPRs above five. • Commonly reported complaints about the process of quantitative fit testing included: discomfort, the heaviness of the device, claustrophobia, noise and communication difficulties.
<p>N95 Filtering Facepiece Respirators Do Not Reliably Afford Respiratory Protection During Chest Compression: A Simulation Study</p> <p>Hwang, et al. 2020 (41)</p>	<ul style="list-style-type: none"> • Subjects: 45 healthcare workers. • Test: Quantitative fit testing (PortaCount Pro+ 8038). • Respirators: N95 respirators (3M 1860, 3M 1870+ and Kimberly Clark 46,727). • Procedure: 44 subjects who passed the baseline quantitative fit testing with any of the respirators underwent further quantitative fit testing while performing real-time chest compression on a mannikin. • Results: <ul style="list-style-type: none"> ○ 73% (n = 32) of the subjects failed at least one of the fit tests during three sessions of chest compression. ○ The number of subjects who failed was significantly higher in the partially passed group (overall fit factor was above 100; however, individual fit factor for some of the eight exercise sessions were below 100) than in the all passed group (94% vs 61%; p = 0.02). ○ Approximately 18% (n = 8) of the subjects experienced mask fit failures, such as strap slipping • Conclusion: Participants passing the quantitative fit testing with the N95 respirator did not guarantee adequate protection against respiratory infections during chest compression.
<p>The Effect on Fit of Multiple Consecutive Donning and Doffing of N95 Filtering Facepiece Respirators</p>	<ul style="list-style-type: none"> • Subjects: 25 employees of an occupational health institute from Johannesburg, South Africa. • Test: Quantitative fit testing (TSI PortaCount Pro+ 8038 with built-in N95 Companion). • Respirators: 3M 1860, 3M VFlex and Kimberly Clark duckbill models 46727 and 46827.

Source	Summary
Peer reviewed sources	
Vuma, et al. 2019 (23)	<ul style="list-style-type: none"> • Procedure: Subjects received training on correct donning of respirators. Novice subjects were fitted with 3M 1860 model with a size that was chosen by the tester, and experienced users were fitted with their currently supplied models in the currently worn sizes. • Results: <ul style="list-style-type: none"> ○ All participants were successfully fitted at the first test. ○ They were instructed to doff and don the same respirator for subsequent tests. Two (8%) failed the second test. Six (24%) failed the third test. Eight (32%) failed the fourth, fifth or sixth test. ○ 12 (48%) failed at least one subsequent test. Among them, five (41.7%) failed all the subsequent tests. Six (50%) passed a subsequent test. • Conclusion: Subsequent donning of a respirator after doffing can impact the fit of the respirator. Adherence to correct donning practices may help to maintain the fit of the respirator.
<p>Are Quantitative Fit Factors Predictive of Respirator Fit During Simulated Healthcare Activities?</p> <p>Sietsema, et al. 2018 (42)</p>	<ul style="list-style-type: none"> • Subjects: 15 subjects with varying facial sizes. • Test: Quantitative fit testing and simulated workplace protection factor test (PortaCount Plus 8020 with N95 Companion). • Respirator: N95 filtering facepiece respirator (3M 1860 or 3M 1860S). • Procedure: Each subject completed initial and final quantitative fast fit tests (five 30-second exercises) and three simulated healthcare activities (CPR, ultrasound and making hospital beds). • Results: <ul style="list-style-type: none"> ○ Overall fit factors from quantitative fit testing and simulated workplace protection factors were highly correlated. Each exercise fit factor was highly correlated with the overall simulated workplace protection factor. ○ Fit factors obtained from normal breathing, head up and down, and talking were most predictive of overall simulated workplace protection factor. • Conclusion: Quantitative fit test results can predict the fit performance of the respirators during simulated work activities.

Source	Summary
Peer reviewed sources	
<p>Influence of facial hair length, coarseness, and areal density on seal leakage of a tight-fitting half-face respirator</p> <p>Floyd, et al. 2018 (25)</p>	<ul style="list-style-type: none"> • Subject: 19 subjects with beards at least 0.500 inches long. • Test: Quantitative fit testing (PortaCount Model 7586). • Respirator: Elastomeric half-face air-purifying respirator (3M 7586) with P100 particulate filters. • Procedures: subjects were given instructions on how to don and doff the respirator and check the seal. Each subject shaved their beards to the lengths of 0.500, 0.250, 0.125 and 0.063, and underwent three fit tests at each length (including after the final shaving-smooth). Facial hair areal density was measured for face seal zone (underneath the chin and either cheek). • Results: <ul style="list-style-type: none"> ○ Quantitative fit factor decreased with beard length. All subjects passed the fit test with a median fit factor of ≥ 100 at smooth and 0.063 inch beard lengths. At 0.125 inch, 98% passed, at 0.250 inches, 81% passed, and at 0.500 inch length, only 58% of subjects passed the fit test. ○ Beard length and areal density were significant and negative predictors of the fit factor. • Conclusion: Fit factor can be negatively influenced by the beard length and areal density. However, even with a beard length up 0.250 inches, a substantial proportion of subjects can obtain adequate fit factor with elastomeric half-face air-purifying respirators.
<p>Comparing the protective performances of 3 types of N95 filtering facepiece respirators during chest compressions</p> <p>Shin, et al, 2017(13)</p>	<ul style="list-style-type: none"> • Subjects: 30 healthcare providers from one emergency department. • Test: quantitative fit testing (PortaCount Plus). • Respirators: 3M 1860 cup-shape, 3M 1870 3-folded, 3M 9332 valved. • Procedure: 30 subjects were randomly allocated to three respirator groups. Subjects were provided with manuals on how to use the respirators and were allowed to practise. Quantitative fit testing was conducted at baseline and during the chest compression exercises using manikins. • Results: <ul style="list-style-type: none"> ○ At baseline, the adequate protection rates (pass rates) for each type of respirators were: 73.7 ± 39.6 (cup-type), 100.00 ± 0.0 (fold-type) and 87.5 ± 30.3 (valve-type). Fold-type respirator had significantly higher adequate protection rate than the cup-type and valve type ($p < 0.05$).

Source	Summary
Peer reviewed sources	
	<ul style="list-style-type: none"> ○ During the chest compression, the adequate protection rates for each type of respirators were: 44.9±42.8 (cup-type), 93.2±21.7 (fold-type) and 59.5±41.7(valve-type). Fold-type respirator had significantly higher adequate protection rates than the cup-type and valve type (p<0.05). ○ There was no significant difference in the quality of chest compression exercises between groups. ○ The adequate protection rates dropped significantly during chest compression than baseline for those wearing cup-type and valve-type respirators. ● Conclusion: Fit factor values could decrease during chest compression, and fold-type respirators performed better during chest compression exercises.
<p>Comparison of two quantitative fit-test methods using N95 filtering facepiece respirators</p> <p>Sietsema and Brosseau, 2016(43)</p>	<ul style="list-style-type: none"> ● Subjects: 16 subjects with varying facial sizes. ● Tests: Quantitative fit testing (PortaCount Plus 8020 with N95 companion), including ambient aerosol condensation nuclei counter quantitative fit test and two-instrument real-time fit test ● Respirators: 3M 1860 and 3M 1860s ● Procedures: Researcher ensured the subject correctly donned a respirator that was perceived to provide the best protection. If subjects failed the fit test during the first exercise session with the first choice of respirator, they were given the other size for further testing. Each subject completed two types of quantitative fit tests in random order. Subjects did not remove respirators in between tests. ● Results: <ul style="list-style-type: none"> ○ The fit factor values obtained during the normal breathing, deep breathing, side-to-side and up-and-down exercises were highly correlated between the two quantitative fit test methods (r>0.7). The overall fit factor values obtained from the two fit tests were moderately correlated (r=0.5, p=0.067). ● Conclusion: The two-instrument real-time fit test could provide similar results to the traditional single instrument fit testing method, especially for exercises involved breathing and side-to-side and up-and-down movements.
<p>Reliability of N95 Respirators for Respiratory Protection Before, During, and After Nursing Procedures</p>	<ul style="list-style-type: none"> ● Subjects: 120 nursing students from Hong Kong, China. ● Tests: Quantitative fit testing (PortaCount Plus+). ● Respirators: N95 filtering facepiece respirators (3M 1860, 3M 1860S or 3M 1870+).

Source	Summary
Peer reviewed sources	
Suen, et al. 2017(14)	<ul style="list-style-type: none"> • Procedure: subjects each underwent quantitative fit testing with the best fitting respirator (confirmed by fit factor at baseline) during and after performing routine nursing procedures. Subjects performed seal checks before tests and were not allowed to readjust respirators in between tests. • Results: <ul style="list-style-type: none"> ○ The average fit factor of the best fitting respirator worn by the participants dropped significantly after nursing procedures (184.85 vs 134.71) as detected by the quantitative fit testing. ○ Significant differences in particle concentration of different sizes (>0.3, >0.4, >1.0 and >4.0 µm) inside the respirator were detected by the portable aerosol spectrometers before, during, and after nursing procedures. • Researchers concluded that body movements during nursing procedures may increase the risk of face seal leakage.
Temporal changes in filtering-facepiece respirator fit Zhuang, et al. 2016(24)	<ul style="list-style-type: none"> • Subject: 229 subjects who were medically cleared and either experienced or inexperienced respirator users at visit 1; 195 subjects at visit 2; 134 subjects at all visits. Data was analysed for the 195 subjects. • Test: Quantitative fit testing (PortaCount Plus without N95 Companion). • Respirator: 7 models of N95 filtering facepiece respirators from 3M and Moldex brands. • Procedure: Subjects performed five individual exercises during fit testing. During visit 1, each subject selected a model of respirator which they felt most comfortable with. They completed three fit tests with the same model, removing the respirator between tests. If the subject passed any of the three consecutive fit tests with the first chosen sample of the model, the subject then went on to test two more samples of the same model. If the subject failed, the subject then went on to test other model samples. Each sample testing involved three consecutive fit testing. During visit 2 to 7, which happened at six month intervals after visit 1, subjects received samples of the filtering facepiece model that were assigned to them and had an acceptable fit at the end of visit 1. Subjects watched instruction videos of the selected model and performed seal checks before the fit tests. • Main outcome measures: fit acceptability, change in fit acceptability, change in face seal leakage and weight and impact of weight change on fit acceptability. An acceptable fit was defined as '90th percentile face seal leakage ≤5% and at least one fit factor ≥100'.

Source	Summary
Peer reviewed sources	
	<ul style="list-style-type: none"> • Results: <ul style="list-style-type: none"> ○ 14, 10, 7, 12, 15 and 16% of subjects had an unacceptable fit with the assigned samples of the respirator model at visit 2 to 7, respectively. ○ The predicted risk of unacceptable fit was 10%, 20% and 25% at 1,2 and 3 years after the initial fit, respectively. ○ Subjects who lost ≥ 20lb were more likely to obtain unacceptable fit during subsequent visits than those who had lower weight loss or gained weight (24% vs 17% vs 7%) • Conclusion: Annual or frequent fit testing may be required to ensure an acceptable fit, especially for those who have lost more than 20lb in weight.
<p>Assessing Real-Time Performances of N95 Respirators for Health Care Workers by Simulated Workplace Protection Fact</p> <p>Kim, et al. 2015(16)</p>	<ul style="list-style-type: none"> • Subjects: 49 healthcare workers. • Tests: Quantitative fit testing and simulated workplace protection factor testing (PortaCount Plus+8038 with N95 Companion). • Respirator: N95 respirators (3M 1860 and 3M 1860S). • Procedure: Subjects were asked to perform simulated scenarios, including patient assessments, suction and intravenous injection (IV) treatment. • Results: <ul style="list-style-type: none"> ○ For quantitative fit testing, 36 out of 49 (73.5%) passed the fit factor criteria ○ The results of quantitative fit testing were found to have a low correlation with Simulated Workplace Protection Factors, with $R(2)=0.32$. ○ The geometric means and geometric standard deviations of simulated workplace protection factor were 68.8 (1.1) for those subjects who passed and 39.6 (1.3) for those who failed. • Conclusion: This study identifies the need for providing different sizes of respirators for healthcare workers and the importance of performing fit tests for healthcare workers regularly.
<p>Effect of Fit Testing on the Protection Offered by n95 Filtering Facepiece Respirators Against</p>	<ul style="list-style-type: none"> • Subjects: 12 subjects. • Tests: Quantitative fit testing (PortaCount Plus with N95 Companion) and protection factor evaluation. • Respirators: Four models of N95 filtering facepiece respirators.

Source	Summary
Peer reviewed sources	
<p>Fine Particles in a Laboratory Setting</p> <p>Reponen, et al. 2011(44)</p>	<ul style="list-style-type: none"> • Procedure: Each subject was trained and guided on how to wear the assigned respirator. Each subject completed quantitative fit testing and particle-size-selective measurement of protection factors. • Results: <ul style="list-style-type: none"> ○ Overall pass-rate for all four models of respirators was 67% (range: 8% to 100%). ○ For all subject-respirator combinations, 29% had a protection factor value below 10 (protection factor ≥ 10 is acceptable). For subject-respirator combinations which passed the fit testing, 9% had a protection factor value below 10. The average protection factor was 1.4 times higher for those who passed the fit testing than all subjects combined. • Conclusions: Passing the fit testing can result in increased protection factor.
<p>Fit Testing Respirators for Public Health Medical Emergencies</p> <p>Brosseau 2010(45)</p>	<ul style="list-style-type: none"> • Subjects: 35 untrained and inexperienced subjects recruited from public. • Test: Quantitative fit testing with (PortaCount Plus 8020 with N95 companion). • Respirators: Two types of N95 filtering facepiece respirators (referred to as A and B). • Procedure: Respirators were fitted with a probe in the centre. No training or assistance were provided to the subjects in donning the respirators. Subjects were given written instructions. Each subject completed two tests with two separate respirator A, and two with two respirator B. • Results: <ul style="list-style-type: none"> ○ 73% of subjects read the written instruction; 97% properly placed the respirator on the face with nose clip on the nose. 80% performed a seal-check, although not being told about the procedure itself. During the fit test, the researcher observed gaps between the facepiece and nose. ○ 34 (97%) subjects obtained a 95% fit factor value greater than 2 (minimum required by the FDA for public health emergency) with Respirator A and 35 (100%) subjects obtained a 95% fit factor value greater than 2 with Respirator B. ○ 3% and 10% of subjects with respirator A and respirator B respectively obtained a fit factor value of 100, which is required for workplaces. • Conclusion: It is important to provide regular training on using respirators and conduct fit testing with employees to ensure satisfactory fit in workplaces.

Source	Summary
Peer reviewed sources	
<p>Evaluation of a Large-Scale Quantitative Respirator-Fit Testing Program for Healthcare Workers: Survey Results</p> <p>Wilkinson, et al. 2010 (19)</p>	<ul style="list-style-type: none"> • Subjects: 6160 healthcare workers from South Australia. • Test: Quantitative fit testing (TSI PortaCount). • Respirators: 3M flat fold N95 model 1870 (regular), Smith & Nephew Proshield N95 (medium and small), and Kimberly-Clark Technol PFR95 Fluidshield (regular and small). • Procedure: The fit tester chose the most appropriate respirator for the subject based on observation of facial characteristics. Subjects completed quantitative fit testing. 4472 workers who were successfully fitted completed a questionnaire after the quantitative fit testing. • Results: <ul style="list-style-type: none"> ○ 3707 (82.9%) passed the quantitative fit testing with the first tested respirator, 551 (12.3%) passed the quantitative fit testing with the second tested respirator after failing the first. 214 (4.8%) passed after three or more tests. ○ Asians (excluding those from South and Central Asia) had the highest failure rate (16.3%). Caucasians had the lowest failure rate (9.8%). ○ Doctors had the highest failure rate (13.4%) while the failure rates for nurses, midwives and allied health personnel were 9.5%, 9.9% and 8.5%, respectively. ○ Healthcare workers with an average nose bridge were more likely to pass the quantitative fit testing than those with a narrow nose bridge (RR: 1.06, 95% CI: 1.04-1.09). ○ Healthcare workers who work in respiratory wards were more likely to pass the quantitative fit testing than those who work in operating rooms (RR:1.11, 95% CI: 1.05-1.16). ○ Testers who had previous experience were more likely to have healthcare workers successfully fitted than testers who had no previous experience (RR: 0.97, 95% CI: 0.94-1.00). ○ Having prior experience or training in respirator use was not significantly related to the pass rate. • Conclusion: Certain facial characters, tester experience and work area of healthcare workers can be associated with the pass rates for quantitative fit testing.
<p>Endotracheal Intubation Using a Direct Laryngoscope and the Protective Performances of Respirators: A Randomised Trial</p>	<ul style="list-style-type: none"> • Subjects: 24 emergency physicians. • Tests: quantitative fit testing (PortaCount Plus 8038 with N95 Companion). • Respirators: 3M 1860 or 1860S (cup-type), 3M 1870 (fold-type without a valve) and 3M 9332 (fold and valve-type).

Source	Summary
Peer reviewed sources	
Lim, et al. 2017 (15)	<ul style="list-style-type: none"> • Procedure: Subjects were randomly allocated to one of three groups with each group using a different respirator model. Subjects were provided with manuals on how to use the respirators and were allowed to practise. Quantitative fit testing was conducted at baseline and during endotracheal intubation on a manikin using a direct laryngoscope. • Results: <ul style="list-style-type: none"> ○ At baseline, the median value for the fit factor for each model of respirators were similar and was 200. There were no significant differences in the adequate protection rates between the three respirator models (p=0.081). ○ During intubation, there was no significant difference in the fit factor obtained from fold-type respirators compared to base line (p=0.105). For both the cup-type and valve-type respirators, the fit factor decreased during intubation compared to baseline (p<0.001). • Conclusion: Fit factor values could decrease during the endotracheal intubation when using cup-type, and valve-type respirators. and fold-type respirators without valves performed better during intubation.
Impact of time and assisted donning on respirator fit Rembialkowski, et al. 2017 (20)	<ul style="list-style-type: none"> • Subjects: 15 subjects with varying facial sizes. • Tests: quantitative fit testing using two side-by-side PortaCount instrument equipped with N95 Companion. • Respirators: 3M 1860 or 1860s filtering facepiece, single size non-certified adhesive mask. • Procedure: Subjects were randomly assigned a first-choice mask but were allowed to try the alternative model. Subjects were first instructed to don the masks according to the manufacturer manuals and then underwent a fit testing. Then they received assistance in donning a new facepiece and underwent another fit testing. Subjects returned for a second visit at least one week later and repeated the same steps as the first visit. • Results: <ul style="list-style-type: none"> ○ During the first visit, 47% and 20% subjects passed the fit test without assistance with the filtering facepiece and adhesive mask, respectively. The pass rates increased to 67% and 47% respectively with assistance.

Source	Summary
Peer reviewed sources	
	<ul style="list-style-type: none"> ○ During the second visit, 53% and 33% subjects passed the fit test without assistance with the filtering facepiece and adhesive mask, respectively. The pass rates increased to 60% and 53%, respectively with assistance. ● Conclusion: Providing assistance with donning masks could increase the fitting performance of the masks.
<p>Quantitative Respirator Fit, Face Sizes, and Determinants of Fit in South African Diagnostic Laboratory Respirator Users</p> <p>Manganyi, et al. 2017 (22)</p>	<ul style="list-style-type: none"> ● Subjects: 562 subjects from South Africa who were diagnostic laboratory employees and had no facial hair. ● Test: Quantitative fit testing (PortaCount). ● Respirator: 3M respirators (69.6%), Kimberly-Clark (23.2%) and other brands (7.2%). 91% of respirators supplied were in medium size. ● Procedure: Subjects were trained in proper donning of respirators. Subjects wore their usual respirator for fit testing. ● Results: <ul style="list-style-type: none"> ○ Only 22% of subjects passed the quantitative fit testing with their current respirators. The mean fit factor for all subjects was 64, below the expected level of 100. ○ A slightly larger percentage of women (80%) than men (74%) failed the fit test. The differences between men and women were significant when 75 men who were not clean-shaven were omitted from the analysis. ○ Asians were more likely to fail the fit test than other races (p=0.002) ○ 41% of subjects were wearing a respirator that was not concordant with their face sizes. ○ 32% of subjects were wearing medium size respirators despite having small face sizes. ○ Subjects with wider nasal root breadth, longer face length, wider face width and wider head circumferences were more likely to pass the fit test than the others. ● Conclusion: A large percentage (78%) of employees were found to have unsatisfactory fit with respirators they usually used. Face size and nasal root breadth could be useful in selecting correct respirator size.
<p>Physiologic and fit factor profiles of N95 and P100 filtering facepiece</p>	<ul style="list-style-type: none"> ● Subjects: 12 healthy non-smoking men. ● Tests: quantitative fit testing (PortaCount Plus with or without N95 Companion). ● Respirators: N95 filtering facepiece (3M 1870), P100 filtering facepiece (3M 8293).

Source	Summary
Peer reviewed sources	
<p>respirators for use in hot, humid environments</p> <p>Kim, et al. 2016 (46)</p>	<ul style="list-style-type: none"> • Procedure: Subjects donned N95 facepieces, performed seal checks, underwent baseline fit testing and performed one hour of treadmill walking in a hot and humid environment (35°C, relative humidity 50%) and underwent post-exercise fit testing. On separate days, they repeated the same steps while wearing either the P100 facepieces or no facepieces at all. • Results: <ul style="list-style-type: none"> ○ There was no significant difference in the pass rates between the two models of facepieces (p=0.61) pre-exercise. N95 facepieces that passed the pre-exercise fit test were more likely to fail the test post-exercise than P100 facepieces that passed pre-exercise (p=0.01) ○ Facial skin covered by the facepieces had significantly higher temperature than when no facepieces were worn (p=0.009). ○ There were no differences in the rectal temperature, global skin temperature, thermal sensation, perception of exertion, microenvironment temperature or humidity between the two models of facepieces and when no facepieces were worn. • Conclusion: P100 filtering facepieces were more likely to maintain a satisfactory fit after one hour of exercises in a hot and humid environment. Wearing those facepieces did not cause significant physiological and perceptual discomfort when compared to when no facepieces were worn.
<p>Comparison of fit factors among healthcare providers working in the Emergency Department Center before and after training with three types of N95 and higher filter respirators</p> <p>Kim, et al. 2019 (18)</p>	<ul style="list-style-type: none"> • Subjects: 22 healthcare providers. • Test: Quantitative fit testing (PortaCount Plus). • Respirators: 3M 1860/S (cup-type), 3M 1870 (fold-type), 3M 9332 (valve-type). • Procedure: Subjects completed fit testing with all three models of respirators before and after receiving training on respirator use. • Results: <ul style="list-style-type: none"> ○ The overall fit factors were significantly higher after the training than before the training; 35 vs 109 for cup-type, 93 vs 171 for fold-type, and 27 vs 83 for valve-type. ○ The adequate protection rates (pass rates) were significantly higher after the training than before training; 12 vs 48 for cup-type, 35 vs 100 for fold-type, and 0 vs 43 for valve-type.

Source	Summary
Peer reviewed sources	
<p>Transocular entry of seasonal influenza-attenuated virus aerosols and the efficacy of n95 respirators, surgical masks, and eye protection in humans</p> <p>Bischoff, et al. 2011 (47)</p>	<ul style="list-style-type: none"> • Conclusion: Provision of training on how to use the respirators could improve the fit performance outcomes of the respirators. <ul style="list-style-type: none"> • Subjects: 28 employees and students of a university. • Tests: Quantitative fit testing (PortaCount Plus). • Respirator: N95 respirator (3M 1860/1860s). • Procedure: Subjects were assigned to six groups - no barrier precaution, ocular exposure only, surgical mask, surgical mask with eye protection, fit-tested respirator and fit-tested respirator with eye protection. Subjects were exposed to aerosolised live attenuated influenza vaccine strains in a test chamber for 20mins. Nasal washes were taken from the subjects after the exposure. • Results: <ul style="list-style-type: none"> ○ No barrier precaution group, influenza was detected in 4 in 4 subjects. ○ Ocular exposure only group, influenza was detected in 3 in 4 subjects. ○ Surgical mask group, influenza was detected in 5 in 5 subjects. ○ Surgical mask with eye protection, influenza was detected in 5 in 5 subjects. ○ Fit-tested N95 group, influenza was detected in 3 in 5 subjects. ○ Fit-tested N95 with eye protection group, influenza was detected in 1 in 5 subjects. • Conclusion: N95 respirators which passed the quantitative fit testing combined with eye protection provided the best guard against influenza virus.

Table 3: Qualitative versus quantitative fit testing

Source	Summary																		
Peer reviewed sources																			
<p data-bbox="138 384 611 528">Comparison of qualitative and quantitative fit-testing results for three commonly used respirators in the healthcare sector</p> <p data-bbox="138 600 416 635">Hon, et al. 2017 (30)</p>	<ul data-bbox="633 384 2063 1054" style="list-style-type: none"> • Subjects: 614 healthcare workers recruited from residential care facilities that did not require use of N95 respirators. • Fit tests: Qualitative fit testing with Bitrex solution and quantitative fit testing with TSI PortaCount Plus Respirator Fit Tester Model 8020 with a N95 Companion. • Respirators: 3M 1860S, 3M 1860, 3M 1870 • Procedure: Subjects underwent sensitivity taste tests before qualitative fit testing. A trained fit-tester assigned one of the three models of the facepieces to a subject based on subject’s face shape and size. Subjects performed and indicated satisfactory seal-checks before fit tests. • Sequence of fit testing: The order of the fit test methods was alternated between subjects. Subjects did not remove or adjust N95 filtering facepieces in transitioning from one fit test to the other. When the qualitative fit test was performed after the quantitative fit test, the adaptor on the respirator which was used to connect a tube to the PortaCount machine was sealed with a cap. • Main outcome measures: Qualitative fit test pass-fail result in which a pass indicated the subject not detecting the Bitrex agent during any of the exercise sessions; quantitative fit test pass-fail result in which a pass indicated that the overall fit factor was ≥ 100; a Kappa (K) value which suggested the level of agreement between the two fit tests. A K value ≥ 0.70 was suggestive of an agreement. • Results: The overall pass-fail results for both the quantitative and the qualitative fit tests were shown in the 2x2 contingency table below. <table border="1" data-bbox="680 1058 2056 1273"> <thead> <tr> <th></th> <th>Qualitative pass</th> <th>Qualitative fail</th> <th>Total</th> <th>K values</th> </tr> </thead> <tbody> <tr> <th>Quantitative pass</th> <td>459</td> <td>4</td> <td>463 (75.4%)</td> <td rowspan="3">0.63</td> </tr> <tr> <th>Quantitative fail</th> <td>69</td> <td>82</td> <td>151 (24.6%)</td> </tr> <tr> <th>Total</th> <td>528 (86%)</td> <td>86 (14%)</td> <td></td> </tr> </tbody> </table>		Qualitative pass	Qualitative fail	Total	K values	Quantitative pass	459	4	463 (75.4%)	0.63	Quantitative fail	69	82	151 (24.6%)	Total	528 (86%)	86 (14%)	
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Quantitative fail	69	82	151 (24.6%)																
Total	528 (86%)	86 (14%)																	

Source	Summary
Peer reviewed sources	
	<ul style="list-style-type: none"> ○ The pass rates for qualitative and quantitative fit tests were 85.3% (n=528) and 74.7%(n=463), respectively. The failure rates for qualitative and quantitative fit tests were 14% (n=86) and 24.4%(n=151), respectively. ○ 459 (75%) subjects passed both the qualitative and quantitative fit tests. 82 (13%) subjects failed both tests. 541(88%) subjects obtained the same results on both tests. ○ The K value was 0.63, which did not meet the recommended threshold of 0.70. When stratified by respirator model, none of the three K values met the threshold. ○ Qualitative fit testing identified 459 out of 463 subjects that passed the quantitative fit testing, indicating a sensitivity value of 0.99. ○ Qualitative fit testing identified 82 out of 151 subjects that failed the quantitative fit testing, indicating a specificity value of 0.54. ○ Among 528 passes identified by qualitative fit testing, 459 (87%) also passed the quantitative fit testing. ○ Among 86 failures identified by qualitative fit testing, 82 (95%) also failed the quantitative fit testing. ● Conclusion: Qualitative fit testing (Bitrex) had a higher pass rate and lower failure rate than quantitative fit testing. Quantitative fit testing was able to detect failures that were passed by the qualitative fit testing. Authors suggest quantitative fit testing should be the preferred testing method. ● Limitation: Subjects were predominately female. The TSI PortaCount model used in this study is no longer commercially available.
<p>Health Care Workers and Respiratory Protection: Is the User Seal Check a Surrogate for Respirator Fit Testing?</p> <p>Danyluk, et al. 2011 (31)</p>	<ul style="list-style-type: none"> ● Subjects: 784 healthcare workers, including 647 naïve subjects with no prior experience of fit testing and 137 experienced subjects. ● Tests: Qualitative fit testing (Bitrex) and quantitative fit testing (TSI Portacount Plus Respirator Fit Tester Model 8020 with a TSI N95-Companion Model 8095). ● Respirators: 3M 1860S, 3M 1860, and 3M 1870.

Source	Summary									
Peer reviewed sources										
	<ul style="list-style-type: none"> • Procedure: Subjects were assigned to one of the three models of filtering facepiece respirators based on the judgement of the professional fit-tester. They were instructed to perform seal checks as per manufacturers’ manual and indicate if the seal was adequate (pass) or inadequate (fail). • Sequence of fit testing: Half of the subjects underwent qualitative fit testing first, followed by quantitative fit testing. The order of fit testing was reversed for the other half. Subjects were not allowed to redon or adjust the respirator in between the two tests. When the qualitative fit testing was performed after the quantitative fit testing, the adaptor on the respirator which was used to connect a tube to the PortaCount machine was sealed with a cap. • Outcome measures: Seal-check pass-fail result, qualitative fit test pass-fail result and quantitative fit test pass-fail results • Results: <ul style="list-style-type: none"> ○ Only four of the 647 naïve subjects (0.62%) identified an inadequate seal during their user seal check. Of the 643 remaining naïve subjects who indicated that they had an adequate face seal prior to fit-testing, 158 (25%) failed the subsequent quantitative fit test and 92 (14%) failed the qualitative fit test ○ All 137 experienced users indicated that they had an adequate seal after performing the user seal check; however, 41 (30%) failed the subsequent quantitative fit test, and 30 (22%) failed the qualitative fit test. ○ The overall pass-fail results for both the quantitative and the qualitative fit tests for those who indicated pass at seal check were shown in the table below. <table border="1" data-bbox="680 1182 2056 1342"> <thead> <tr> <th></th> <th>Qualitative</th> <th>Quantitative</th> </tr> </thead> <tbody> <tr> <td>Pass</td> <td>658 (84%)</td> <td>581 (74.5%)</td> </tr> <tr> <td>Fail</td> <td>122 (16%)</td> <td>199 (25.5%)</td> </tr> </tbody> </table>		Qualitative	Quantitative	Pass	658 (84%)	581 (74.5%)	Fail	122 (16%)	199 (25.5%)
	Qualitative	Quantitative								
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Fail	122 (16%)	199 (25.5%)								

Source	Summary			
Peer reviewed sources				
	<table border="1" data-bbox="683 384 2056 440"> <tr> <td data-bbox="683 384 1115 440">Total</td> <td data-bbox="1115 384 1585 440">780</td> <td data-bbox="1585 384 2056 440">780</td> </tr> </table> <ul style="list-style-type: none"> ○ The pass rates for qualitative and quantitative fit tests were 84% (n=658) and 74.5%(n=581), respectively. The failure rates for qualitative and quantitative fit tests were 16% (n=122) and 25.5% (n=199), respectively. ● Conclusions: User seal-checks can be inadequate in identifying poorly fitted respirators. Qualitative fit testing (Bitrex) had a higher pass rate and lower failure rate than quantitative fit testing. 	Total	780	780
Total	780	780		
<p>Comparison of Performance of Three Different Types of Respiratory Protection Devices</p> <p>Lawrence, et al. 2009 (29)</p>	<ul style="list-style-type: none"> ● Subjects: 25 test subjects with varying facial sizes. ● Tests: Qualitative fit testing with Bitrex and saccharin solutions, quantitative fit testing with TSI PortaCount Plus with a N95 Companion, simulated workplace protection factor test with TSA PortaCount Plus. ● Respirators: 15 models of N95 filtering-facepiece respirators (various manufacturers), 15 models of N95 elastomeric half-facepiece respirators (various manufacturers), and six surgical masks. ● Procedure: Subjects were assigned a device based on their facial measurements. In between six simulated workplace protection factor tests and three fit tests, subjects removed the devices to be reconfigured by a technician and redonnned. All subjects performed a user seal-check as per manufacturers' instructions ● Sequence of fit testing: not mentioned ● Main outcome measures: Simulated workplace protection factor, which is 'a measure of the protection received by an individual from a respirator' in a simulated workplace environment. A respirator was considered to provide adequate protection if the 5th percentile simulated workplace protection factor was ≥10; fit test pass-fail rate; and h-value, which is a measure of assessing the respirator performance. A h-value of ≥0.95 is indicative of 95% of the wearers of the half-facepiece respirators have obtained adequate level of protection. ● Results: The mean simulated workplace protection factor 5th percentile results by fit test method are presented in the table below. 			

Source	Summary							
Peer reviewed sources								
	The value for simulated workplace protection factor 5 th percentile by fit test method (a value of ≥10 indicates adequate protection)							
		Without fit testing	Qualitative with Bitrex		Qualitative with saccharin		Quantitative	
			Pass	Fail	Pass	Fail	Pass	Fail
	N95 filtering facepieces	3.3	7.9	3.0	11.0	3.0	20.5	2.7
	N95 elastomeric facepieces	7.3	11.1	6.3	11.7	6.2	13.0	4.4
	Surgical masks	1.2						
<ul style="list-style-type: none"> ○ Before any fit-testing, N95 elastomeric facepiece respirators provided the highest level of protection and surgical masks provided the lowest level of protection. None of the three groups of masks provided the expected level of protection (5th percentile of 10 or above). ○ For either types of facepiece respirators (when analysed together), there were no significant differences in the level of protection between the passes of either of the three types of fit tests. ○ For N95 filtering facepieces (when analysed separately), they provided significantly higher level of protection after passing the quantitative fit testing than the level of protection after passing the qualitative fit testing (Bitrex) (p=0.0011). There was no significant difference in the level of protection between passes of qualitative fit testing (Bitrex) or qualitative fit testing (saccharin). ○ For N95 elastomeric facepiece respirators (when analysed separately), there were no significant differences in the level of protection between the passes of any of the three fit tests. 								

Source	Summary																												
Peer reviewed sources																													
	<ul style="list-style-type: none"> ○ Fit test pass-fail results for different models of facepieces are demonstrated in the table below. <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th></th> <th colspan="2">Qualitative with Bitrex</th> <th colspan="2">Qualitative with saccharin</th> <th colspan="2">Quantitative</th> </tr> <tr> <th></th> <th>Pass</th> <th>Fail</th> <th>Pass</th> <th>Fail</th> <th>Pass</th> <th>Fail</th> </tr> </thead> <tbody> <tr> <td>N95 filtering facepieces</td> <td>42</td> <td>332</td> <td>43</td> <td>331</td> <td>82</td> <td>292</td> </tr> <tr> <td>N95 elastomeric facepieces</td> <td>119</td> <td>253</td> <td>129</td> <td>243</td> <td>227</td> <td>145</td> </tr> </tbody> </table> <ul style="list-style-type: none"> ○ Pass rates for qualitative fit testing (Bitrex), qualitative fit testing (Saccharin) and quantitative fit testing with both the elastomeric and filtering facepiece respirators were 11.2%, 11.5% and 30%, respectively. The overall pass rate for elastomeric facepiece respirators using any of the fit tests was higher than the filtering facepiece respirators (43% vs 15%). ○ The h-value for surgical masks, N95 FFRs and N95 elastomeric facepiece respirators were 0.003, 0.74 and 0.92 respectively. ● Conclusion: Elastomeric facepiece respirators with N95 filters provided the highest-level protection, followed by N95 filtering facepieces. Surgical masks provided the least level of protection. N95 filtering facepieces provided a higher level of protection which was above the expected level after passing the qualitative fit test (saccharin) and quantitative fit test. N95 elastomeric facepiece respirators provided a higher level of protection after passing either the qualitative fit test (Bitrex or saccharin) or quantitative fit testing, which was above the expected protection level. Qualitative fit testing (Bitrex or saccharin) had a 		Qualitative with Bitrex		Qualitative with saccharin		Quantitative			Pass	Fail	Pass	Fail	Pass	Fail	N95 filtering facepieces	42	332	43	331	82	292	N95 elastomeric facepieces	119	253	129	243	227	145
	Qualitative with Bitrex		Qualitative with saccharin		Quantitative																								
	Pass	Fail	Pass	Fail	Pass	Fail																							
N95 filtering facepieces	42	332	43	331	82	292																							
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Source	Summary
Peer reviewed sources	
	<p>lower pass rate than quantitative fit testing, which may necessitate repeat testing and increase associated costs and time. N95 elastomeric facepiece respirators were easier to fit and provided a higher level of protection, indicating they may potentially reduce the overall costs associated with workplace protection programs.</p>
<p>Errors associated with three methods of assessing respirator fit</p> <p>Coffey, et al. 2006 (33)</p>	<ul style="list-style-type: none"> • Subjects: 25 subjects with varying facial sizes. • Tests: Qualitative fit testing (Bitrex and saccharin), quantitative fit testing (TSI PortaCount Plus with N95 Companion) and simulated workplace protection factor test (PortaCount Plus) • Respirators: 15 models of N95 filtering facepiece respirator and 15 models of N95 elastomeric facepiece respirator • Procedure: Subjects were assigned a device based on their facial measurements. In between different exercise sessions of simulated workplace protection factor tests and three fit tests, subjects removed the devices to be reconfigured by the technician and redonned. All subjects performed a user seal-check as per manufacturers' instructions • Sequence of fit testing: Not mentioned. Either a sampling probe or sampling adaptor was used for quantitative fit testing and the simulated workplace protection factor testing. • Main outcome measures: 5th percentile simulated workplace protection factor value, with a value of ≥ 10 was considered a threshold of providing adequate protection; the α error (%), which was defined as the proportion of subjects whose respirators provided adequate level of protection (Simulated Workplace Protection Factor 5th percentile value above 10) however did not pass the fit test. The β error (%), which was defined as the proportion of subjects whose respirators did not provide adequate level of protection, however, passed the fit test. The alpha (α) and beta (β) errors were also reported for the simulated fit test program, 'in which a wearer is given up to three trials with one respirator model to pass a fit test before moving onto another model'. • Results: The α and β errors for each test is shown in the table below.

Source	Summary								
Peer reviewed sources									
		Qualitative with Bitrex		Qualitative with saccharin		Quantitative		Simulated fit test program	
		α error (%)	β error (%)	α error (%)	β error (%)	α error (%)	β error (%)	α error (%)	β error (%)
	All facepieces combined	71	8	68	8	40	9	29	19
	N95 filtering	83	5	81	3	60	3	48	10
	N95 elastomeric	62	14	60	19	26	21	44	13
	<ul style="list-style-type: none"> ○ Only quantitative fit testing met the accuracy goal for α error being ≤50% when all facepieces were analysed together or only N95 elastomeric facepieces were analysed. Both the qualitative and quantitative fit tests met the β error being ≤5% with N95 filtering facepieces only. ● Conclusion: Qualitative fit testing (Bitrex or saccharin) had a higher α error value than quantitative fit testing, and was therefore more likely to fail a subject whose respirator provided adequate protection. Simulated fit test program had the highest β error value (19%), indicating that approximately one in five wearers may pass the tests even when the protection level was inadequate. These errors can be sensitive to the types or models of the respirators (N95 filtering facepiece respirators vs N95 elastomeric). 								
Physiologic effects and measurement of carbon dioxide and oxygen levels during qualitative respirator fit testing	<ul style="list-style-type: none"> ● Subjects: 20 subjects with no facial hair. ● Tests: Quantitative fit testing (TSI PortaCount 8020, with N95 Companion for N95 respirator), qualitative fit testing, ● Respirators: Full facepiece respirators (Scott O-Vista) and N95 filtering facepiece respirators (MSA Affinity Pro N95). 								

Source	Summary																																			
Peer reviewed sources																																				
Laferty and Mckay 2005(35)	<ul style="list-style-type: none"> • Procedure: Subjects performed and indicated satisfactory seal checks before fit tests. TSI Fit Test Probe Kit was used to connect N95 respirators to PortaCount machine. Subjects removed the respirator for at least two minutes in between fit tests. CO₂ and O₂ levels were measured 30 seconds after each fit test. • Sequence of fit testing: Subjects completed quantitative and qualitative fit testing with the full facepiece first, followed by quantitative and qualitative fit testing with the N95 filtering facepiece. • Main outcome measures: Mean CO₂ and O₂ level inside the two types of respirators and the test hood; temperature inside the test hood during the qualitative fit testing. • Results: 19 subjects passed the quantitative fit testing with the full facepiece respirator. 18 subjects passed the quantitative with the filtering facepiece respirator. The mean CO₂ and O₂ level inside the two types of respirators and the test hood at the end of each test were demonstrated in the tables below. <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th></th> <th colspan="4">Mean and standard deviation of CO₂ levels inside the respirator and test hood</th> </tr> <tr> <th></th> <th colspan="2">Quantitative fit testing</th> <th colspan="2">Qualitative fit testing</th> </tr> <tr> <th></th> <th>Mean (%)</th> <th>SD (%)</th> <th>Mean (%)</th> <th>SD (%)</th> </tr> </thead> <tbody> <tr> <td>Full facepiece</td> <td>2.1</td> <td>0.4</td> <td>3.2</td> <td>0.4</td> </tr> <tr> <td>N95 filtering facepiece</td> <td>2.8</td> <td>0.5</td> <td>4.2</td> <td>0.4</td> </tr> <tr> <td>Test hood (with full facepiece)</td> <td></td> <td></td> <td>1.4</td> <td>0.4</td> </tr> <tr> <td>Test hood (with N95)</td> <td></td> <td></td> <td>2.2</td> <td>0.7</td> </tr> </tbody> </table>		Mean and standard deviation of CO ₂ levels inside the respirator and test hood					Quantitative fit testing		Qualitative fit testing			Mean (%)	SD (%)	Mean (%)	SD (%)	Full facepiece	2.1	0.4	3.2	0.4	N95 filtering facepiece	2.8	0.5	4.2	0.4	Test hood (with full facepiece)			1.4	0.4	Test hood (with N95)			2.2	0.7
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Peer reviewed sources																						
	<ul style="list-style-type: none"> Conclusions: Wearing a respirator inside a test hood may have contributed to the elevated CO₂ level and decreased O₂ level inside the respirator. Professionals conducting fit testing, especially qualitative fit testing, should be aware of the changes in the CO₂ and O₂ levels which may cause physiological discomfort for people. Special attention may need to be paid to elderly, pregnant women, people with pulmonary or cardiac disease, and people with anxiety, panic disorders and claustrophobia. 																					
<p>Fitting Characteristics of Eighteen N95 Filtering-Facepiece Respirators</p> <p>Coffey, et al. 2004(32)</p>	<ul style="list-style-type: none"> Subjects: 25 subjects with varying facial sizes Tests: Qualitative fit testing (Bitrex), qualitative fit testing (saccharin), quantitative fit testing (PortaCount Plus corrected for filter penetration), quantitative fit testing (PortaCount Plus and N95-Companion) and quantitative fit testing (generated aerosol with Dynatech Frontier Model 260) and simulated workplace protection factor testing (PortaCount Plus). Respirators: 18 models of N95 filtering facepiece respirators from various manufacturers. Procedures: Not all models were tested with saccharin and generated aerosol methods. Main outcome measures: Simulated workplace protection factor 5th percentile value (expected value ≥10), the shift average simulated workplace protection factor, the h-value (proportion of donnings resulting in an adequate level of protection), and the assignment error (the percentage of respirator users who, even though they pass a fit-test, would mistakenly be assigned a poorly-fitting respirator). Results: The simulate workplace protection factor 5th percentile results by fit test method are presented in the table below. <table border="1" data-bbox="633 1094 2056 1343"> <thead> <tr> <th></th> <th colspan="6">Mean simulated workplace protection factor 5th percentile value</th> </tr> <tr> <th></th> <th>Without fit testing</th> <th>Bitrex</th> <th>saccharin</th> <th>Companion</th> <th>PortaCount Plus corrected</th> <th>Generated aerosol</th> </tr> </thead> <tbody> <tr> <td>Pass</td> <td>2.9</td> <td>7.4</td> <td>6.9</td> <td>74.5</td> <td>14.6</td> <td>21.6</td> </tr> </tbody> </table>		Mean simulated workplace protection factor 5 th percentile value							Without fit testing	Bitrex	saccharin	Companion	PortaCount Plus corrected	Generated aerosol	Pass	2.9	7.4	6.9	74.5	14.6	21.6
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	Without fit testing	Bitrex	saccharin	Companion	PortaCount Plus corrected	Generated aerosol																
Pass	2.9	7.4	6.9	74.5	14.6	21.6																

Source	Summary						
Peer reviewed sources							
	Fail	(1.3-48)	2.1	1.9	2.3	2.7	4.7
	Fit test pass-fail results						
	Bitrex	saccharin	Companion	PortaCount Plus corrected	Generated aerosol		
Pass	155 (33%)	55(25%)	146(31%)	76(16%)	30(12%)		
Fail	294(65.5%)	165(75%)	303(68%)	373(83%)	220(88%)		
	<ul style="list-style-type: none"> ○ Three models of respirators had a simulated workplace protection value ≥ 10 without any fit testing. ○ Passes of quantitative fit testing (Companion) had the highest simulated workplace protection value of 74.5, followed by 21.6 of quantitative fit testing (generated aerosol) and 14.6 of quantitative (PortaCount Plus corrected for filter penetration). Passes of qualitative fit testing with Bitrex and saccharin had the lowest mean simulated workplace protection factor, which were below the expected level. ○ There was a wide variation in the pass rates for different models of respirators when using the same method of fit testing, with qualitative fit testing (Bitrex) having a range of 13-52% with a mean of 33% and quantitative fit testing (PortaCount Plus N95 Companion) having a range of 0-88% with a mean of 31%.(6) ○ The h-values for all models combined was 0.74. ○ Assignment errors for each test were: 8.9 (Bitrex), 8.2 (Companion), 8.1 (saccharin), 6.6 (generated aerosol), and 5.9 (PortaCount Plus). ● Conclusion: It is possible that some models of respirators (three models in this study) can obtain higher level of protection for subjects even without any fit testing than others which passed certain fit testing. 						

Source	Summary												
Peer reviewed sources													
	<p>Passing a qualitative fit test may not necessarily result in adequate protection. Generally, respirators passing a fit test provided a higher level of protection than those who failed the same fit test.</p>												
<p>Comparison of three commercially available fit-test methods</p> <p>Janssen, et al. 2002 (28)</p>	<ul style="list-style-type: none"> • Subjects: 25 experienced fit test subjects with varying facial sizes. • Tests: Quantitative fit testing (PortaCount Plus Respirator Fit Tester), quantitative fit testing (Fit Tester 3000) and qualitative fit testing (Bitrex). • Respirators: 3M 6X00, 3M 700X, the MSA Comfo II. • Procedures: Subjects were assigned to a respirator based on the observation of their facial sizes. During the first day of testing, subjects were allowed to perform seal checks, however, this was not allowed from the second day. 3M respirators were fitted with specific quantitative fit testing adapters for quantitative fit testing. • Sequences of the tests: Sequences were randomised. Subjects did not remove facepieces in between fit tests. • Main outcome measures: Fit test pass-fail rates. • Results: The pass and fail results for each test is shown in table below. <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th></th> <th>Quantitative with PortaCount</th> <th>Quantitative with Fit Tester</th> <th>Qualitative with Bitrex</th> </tr> </thead> <tbody> <tr> <td>Pass (%)</td> <td>10 (40%)</td> <td>1(4%)</td> <td>2(12%)</td> </tr> <tr> <td>Fail(%)</td> <td>15(60%)</td> <td>24(96%)</td> <td>22(88%)</td> </tr> </tbody> </table> <ul style="list-style-type: none"> ○ Quantitative fit testing (Fit Tester) was able to identify 87% failures identified by quantitative fit testing (PortaCount). Qualitative fit testing (Bitrex) was able to identify 79% of the failures identified by QNFT (PortaCount). 		Quantitative with PortaCount	Quantitative with Fit Tester	Qualitative with Bitrex	Pass (%)	10 (40%)	1(4%)	2(12%)	Fail(%)	15(60%)	24(96%)	22(88%)
	Quantitative with PortaCount	Quantitative with Fit Tester	Qualitative with Bitrex										
Pass (%)	10 (40%)	1(4%)	2(12%)										
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Source	Summary		
Peer reviewed sources			
<p>Comparison of five methods for fit-testing N95 filtering-facepiece respirators</p> <p>Coffey, et al. 2002 (34)</p>	<ul style="list-style-type: none"> • Conclusion: All three methods unanimously agreed on pass or fail of a case 75% of the time. Qualitative fit testing (Bitrex) had a lower pass rate than quantitative fit testing (PortaCount). • Subjects: 25 subjects with varying facial sizes. • Tests: Qualitative fit testing (Bitrex), qualitative fit testing (saccharin), quantitative fit testing (ambient aerosol fit test with PortaCount Plus), quantitative fit testing (ambient aerosol with PortaCount Plus and N95-Companion), quantitative fit testing (generated aerosol with Dynatech Frontier Model 260 and simulated workplace protection factor testing (PortaCount Plus). • Respirators: 18 models of respirators from different manufacturers. • Procedures: Subjects were assigned a device based on their facial measurements. In between different exercise sessions of simulated workplace protection factor tests and three fit tests, subjects removed the devices to be reconfigured by the technician and redonned. All subjects performed a user seal-check as per manufacturers' instructions. • Sequence of fit testing: Not mentioned. A sampling probe was inserted into each respirator for quantitative fit testing. • Main outcome measures: 5th percentile simulated workplace protection factor value, with a value of ≥ 10 was considered a threshold of providing adequate protection; the α error (%), which was defined as the proportion of subjects whose respirators provided adequate level of protection (Simulated Workplace Protection Factors 5th percentile value above 10) however did not pass the fit test. The β error (%), which was defined as the proportion of subjects whose respirators did not provide adequate level of protection, however, passed the fit test. Assignment error (%), which was defined as 'the percentage of respirator wearers mistakenly assigned an ill-fitting respirator'. • Results: The α and β errors for each test is shown in the table below. <table border="1" data-bbox="636 1259 2058 1316"> <tr> <td data-bbox="636 1259 831 1316"></td> <td data-bbox="831 1259 2058 1316">Fit test pass-fail results</td> </tr> </table>		Fit test pass-fail results
	Fit test pass-fail results		

Source	Summary					
Peer reviewed sources						
		Bitrex	Saccharin	Companion	Ambient aerosol	Generated aerosol
	α error (%)	51	56	57	75	84
	β error (%)	11	9	9	4	3
	Assignment error (%)	8.99	8.09	8.21	5.92	6.59
	<ul style="list-style-type: none"> ○ The accuracy goal for α error was ≤ 50. None of the methods met the accuracy goal, with qualitative fit testing (Bitrex) method having the closest value. ○ The accuracy goal for β error was ≤ 5. Only the quantitative fit testing (generated aerosol) and quantitative fit testing (ambient aerosol) methods met the accuracy goal. ● Conclusion: β error value was considered to be more important as it indicated the proportion of inadequate protection by respirators that passed the fit tests. The quantitative fit testing (generated aerosol) and quantitative fit testing (ambient aerosol) had the lowest β value and therefore, were least likely to pass poorly fitted respirators. Qualitative fit testing (Bitrex) method had the lowest α error value, meaning that it was least likely to fail a respirator that provided adequate protection. When taking into consideration the all three types of errors, quantitative fit testing (ambient aerosol) method was considered to be best at identifying poorly fitted respirators. 					
Comparison of N95 Disposable Filtering Facepiece Fits Using Bitrex Qualitative and TSI Portacount® Quantitative Fit Testing	<ul style="list-style-type: none"> ● Subject: 79 subjects recruited from general population ● Tests: Quantitative fit testing (TSI PortaCount with N95 companion) and qualitative fit testing (Bitrex). ● Respirators: Filtering facepiece respirators including 3M 8210, Gerson 2737, MSA Ultrafit Affinity, and Wilson N9510. 					

Source	Summary																
Peer reviewed sources																	
Clapham 2000 (27)	<ul style="list-style-type: none"> Procedures: The size of the respirator for each subject was decided by a trained fit-tester based on the subject’s facial size. Both the fit-tester and subject indicated satisfactory fit before the fit tests. During quantitative fit testing, each respirator was fitted with predesigned rivets to allow a sampling probe to be inserted. The respirator was connected to the sampling pendant on TSI PortaCount machine via a detachable tygon interconnect tube. During the qualitative fit testing, the opening of the tube connecting to the pendant was removed from the machine and was sealed. Sequence of fit tests: Fit tests were performed in a random order. Subjects did not remove the respirators in between tests. Main outcome measures: Fit test pass-fail results. Results: The pass and fail results for each test is shown in table below. <table border="1" data-bbox="680 758 2045 975"> <thead> <tr> <th></th> <th>Qualitative pass</th> <th>Qualitative fail</th> <th>Total</th> </tr> </thead> <tbody> <tr> <td>Quantitative pass</td> <td>6</td> <td>38</td> <td>44 (56%)</td> </tr> <tr> <td>Quantitative fail</td> <td>5</td> <td>30</td> <td>35 (44%)</td> </tr> <tr> <td>Total</td> <td>11 (14%)</td> <td>68 (86%)</td> <td></td> </tr> </tbody> </table> <ul style="list-style-type: none"> Quantitative fit testing had a lower failure rate than qualitative fit testing (44% vs 86%). Most subjects (88%) failed the qualitative fit testing before undertaking more rigorous breathing exercises. Qualitative fit testing was able to detect 6 out of 44 subjects that passed the quantitative fit testing, indicating a sensitivity value of 0.14. Qualitative fit testing was able to detect 30 out of 35 subjects that failed the quantitative fit testing, indicating a specificity value of 0.86. Among 11 passes identified by qualitative fit testing, 6 (55%) were true passes (identified by quantitative fit testing), indicating a predictive positive value of 0.55. 		Qualitative pass	Qualitative fail	Total	Quantitative pass	6	38	44 (56%)	Quantitative fail	5	30	35 (44%)	Total	11 (14%)	68 (86%)	
	Qualitative pass	Qualitative fail	Total														
Quantitative pass	6	38	44 (56%)														
Quantitative fail	5	30	35 (44%)														
Total	11 (14%)	68 (86%)															

Source	Summary
Peer reviewed sources	
	<ul style="list-style-type: none"> • Among 68 failures identified by qualitative fit testing, 30 (45%) were true failures (identified by quantitative fit testing), indicating a predictive negative value of 0.45. • Conclusion: Qualitative fit testing using Bitrex solution had a higher rate of failure and a lower pass rate compared to quantitative fit testing. Qualitative fit testing had a low sensitivity in identifying a pass that was determined by quantitative fit testing. However, it may be useful in identifying poorly fitting respirators.

Table 4 Fit checking versus fit testing

Source	Summary
Peer reviewed sources	
<p>Fit Characteristics of N95 Filtering Facepiece Respirators and the Accuracy of the User Seal Check among Koreans</p> <p>Huh, et al. 2018 (21)</p>	<ul style="list-style-type: none"> • Subjects: 221 subjects recruited from a military hospital and with varying facial sizes. • Test: Quantitative fit testing with PortaCount Plus+ 8038. • Respirators: 3M 1860/1860S, Maskin MS6115, 3M 1870+, Kimberley-Clark (K-C) 46727. • Procedures: Subjects performed seal checks according to manufacturers’ manual and were given three chances to adjust the respirators if they perceive a leakage before marking the seal check result as failure. Subjects then completed quantitative fit testing. • Results: <ul style="list-style-type: none"> ○ 3M 1870+ model had the highest pass rate of 46%, followed by 3M 1860/s of 45.5%, Kimberly-Clark 46727 of 19.9% and Maskin MS6115 OF 15.8%. ○ Male gender was significantly associated with higher pass rates with 3M and Kimberly-Clark models. ○ With 3M 1860/s, larger facial size was significantly associated with higher pass rates. ○ In 17.5% to 53.8% cases, user seal checks correctly identified a leakage. In 31.8% to 56.4% cases, a user seal check had the same pass-fail result as fit test. • Conclusion: The fit test pass rates for four commonly used respirators were low for Korean participants. User seal checks can be inadequate in identifying leakage.
<p>Evaluation of the User Seal Check on Gross Leakage Detection of 3 Different Designs of N95 Filtering Facepiece Respirators</p> <p>Lam, et al. 2016 (48)</p>	<ul style="list-style-type: none"> • Subjects: 638 nursing students • Test: Quantitative fit testing (PortaCount Pro+8038) • Respirators: 3M 1860s, 3M 1862, and Kimberly-Clark 46827 • Procedure: Subjects received training on donning the respirators and performing user seal checks. Subjects performed seal checks before completing fit testing (normal and deep breathing exercises) with three types of respirators. • Results: <ul style="list-style-type: none"> ○ 25.7%, 20.4% and 24.5% subjects indicated pass with seal-checks with 3M 1860s, 3M 1862 and Kimberly-Clark respirator, respectively. ○ 31.0%-39.2% subjects passed the quantitative fit-testing with the 3M respirators and 65.4%-65.8% subjects passed the fit testing with the Kimberly-Clark respirator.

Source	Summary
Peer reviewed sources	
	<ul style="list-style-type: none"> ○ User seal checks were able to identify true actual leakage (identified by quantitative fit testing) in 27.7%, 22.1% and 26.9% cases respectively with 3M 1860, 3M 1862 and Kimberly-Clark 46827 models. ○ User seal checks were able to identify actual absence of gross leakage (identified by quantitative fit testing) in 75.5%, 80.5% and 80.2% cases respectively with 3M 1860, 3M 1862 and Kimberly-Clark 46827. ● Conclusion: User seal checking may not have the high sensitivity in identifying gross leakage, however, it may still be useful in reinforcing correct use of respirators.
<p>Evaluation of the Benefit of the User Seal Check on N95 Filtering Facepiece Respirator Fit</p> <p>Viscusi, et al. 2012 (49)</p>	<ul style="list-style-type: none"> ● Subjects: 11 subjects. ● Test: Quantitative fit testing. ● Respirators: 3M 1860 (cup), 3M 1870 (flat-fold), and Kimberly Clark PFR95-270 (duckbill). ● Procedure: Subjects were randomly instructed either to perform or not to perform seal checks before fit testing with 20 samples of each respirator model. ● Results: <ul style="list-style-type: none"> ○ The average pass rates for quantitative fit testing when not performing user seal-checks vs performing user seal-checks were: 72% vs 82% for 3M 1860, 97% vs 95% for 3M 1870 and 66% vs 86% (p<0.05) for Kimberly-Clark PFR95-270. ● Conclusions: For some respirator models, performing user seal checks may improve the fit performance of previously fitted respirators.
<p>Does training in performing a fit check enhance N95 respirator efficacy?</p> <p>Or, et al. 2012 (36)</p>	<ul style="list-style-type: none"> ● Subject: 82 first year nursing students with no experience of fit testing or fit checking. ● Protective device: A 3M N95 respirator that was commonly used in Hong Kong. ● Procedure: Subjects were divided into four groups <ul style="list-style-type: none"> ○ Group A: quantitative fit testing (PortaCount) and training on fit checking ○ Group B: training on fit checking ○ Group C: quantitative fit testing (PortaCount) ○ Group D: no fit testing and no training on fit checking.

Source	Summary
Peer reviewed sources	
	<p>All subjects performed personal respirator sampling test while wearing the N95 respirator and undertaking beside nursing procedures.</p> <ul style="list-style-type: none"> • Results: <ul style="list-style-type: none"> ○ Groups (A and B) which had training in fit checking had higher fit factors than groups (C and D) which did not receive training. • Conclusion: Providing training on performing fit checks can improve the fitting outcome.
<p>Respiratory Protection by Respirators: The Predictive Value of User Seal Check for the Fit Determination in Healthcare Settings</p> <p>Lam, et al. 2011(50)</p>	<ul style="list-style-type: none"> • Subjects: 349 nursing students • Test: Quantitative fit testing (PortaCount Pro+8038) • Respirators: 3M 1860s and 3M 1862 • Procedure: Subjects performed user seal-checks before fit testing. • Results: <ul style="list-style-type: none"> ○ For 3M 1860s model, user seal check indicated leakage in 11.5% cases and quantitative fit testing identified leakage in 35% cases. User seal check sensitivity and specificity values were ○ For 3M 1862 model, user seal check indicated leakage in 9.7% cases and quantitative fit testing identified leakage in 41% cases. ○ Male subjects had a higher pass-rate than female subjects. • Conclusion: User seal-checking may not have the high sensitivity in identifying gross leakage, however, it may still be useful in reinforcing correct use of respirators.
<p>Sensitivity and Specificity of the User-Seal-Check in Determining the Fit of N95 Respirators</p> <p>Lam, et al. 2011(51)</p>	<ul style="list-style-type: none"> • Subjects: 204 undergraduate nursing students. • Tests: Quantitative fit testing (PortaCount Pro 8038). • Respirators: 3M 1860S and 3M 1862. • Procedure: Subjects performed a seal check before undertaking fit testing with both respirator models. • Results: <ul style="list-style-type: none"> ○ User seal checks with 3M 1860s and 3M 1862 models had sensitivity values of 15.2% and 23.0% respectively, indicating the proportions of failed cases correctly identified by seal checks. ○ User seal checks with 3M 1860s and 3M 1862 models had specificity values of 88.8% and 89.7% respectively, indicating the proportion of passed cases correctly identified by seal checks.

Source	Summary
Peer reviewed sources	
<p>Predictive value of the user seal check in determining half-face respirator fit</p> <p>Derrick, et al. 2005(52)</p>	<ul style="list-style-type: none"> ○ Over 80% of subjects passed the fit tests with either of the respirators. ● Conclusion: The user seal check was not found to be reliable as a substitute for quantitative fit testing. <ul style="list-style-type: none"> ● Subjects: 263 nurses from Hong Kong, China. ● Test: Quantitative fit testing (PortaCount Plus). ● Respirators: 3M 1860s, 3M 9210 or 3M 8233. ● Procedure: A retrospective review of a mask fitting programme in a hospital. Subjects were asked to perform seal checks on respirator masks before completing quantitative fit testing. ● Results: In 18-31% cases, seal checks wrongly indicated a correct fit and in 21-40% cases, seal checks wrongly indicated a failed fit. ● Conclusion: User seal checks can be inaccurate in indicating the fit of respirator masks.

Source	Summary
Peer reviewed sources	
<p>Determination of known exhalation valve damage using a negative pressure user seal check method on full facepiece respirators</p> <p>Delaney, et al. 2003(53)</p>	<ul style="list-style-type: none"> • Subjects: 26 subjects recruited from a university. • Tests: Quantitative fit testing (PortaCount Plus 8020) and quantitative fit testing (Dynatech Nevada FitTester 3000), in-mask pressure check (Respirator Leak Checker). • Respirators: Probed, full-facepiece respirator (North 7600 series). • Procedure: Subjects were instructed to on how to use proper respirators and perform negative pressure user seal checks before donning the appropriate size facepiece. Subjects performed seal checks and fit testing with facepieces with undamaged valves first. Subjects who passed both the fit tests repeated the seal checks and fit testing with three more warped/slits/dirty facepieces. A fit factor above 500 was considered as a pass. • Results: <ul style="list-style-type: none"> ○ All subjects indicated satisfactory seal checks with undamaged valves, and all obtained fit factors above 500 during fit tests. ○ 25 (95%) subjects indicated satisfactory seal checks with warped valves, and all failed the fit tests. ○ 73% subjects indicated satisfactory seal checks with slit valves, and all failed the fit tests. ○ 65% subjects indicated satisfactory seal checks with dirty valves, and all failed the fit tests. • Conclusion: Negative pressure user seal checks were unhelpful in identifying damaged valves. Regular respirator inspection, along with seal checks and periodic fit testing are necessary components of a respiratory protection program.

Table 5: COVID-19 advice in Australia – Fit testing

Source organisation and title	Recommendations
<p>Australian Department of Health - Guidance on the minimum recommendations for the use of</p>	<p>Fit-checking is the minimum standard for each occasion of use of a PFR.</p>



Rapid evidence checks are based on a simplified review method and may not be entirely exhaustive, but aim to provide a balanced assessment of what is already known about a specific problem or issue. This brief has not been peer-reviewed and should not be a substitute for individual clinical judgement, nor is it an endorsed position of NSW Health.

Source organisation and title	Recommendations
<p>personal protective equipment (PPE) in hospitals during the COVID-19 outbreak</p> <p>14 February 2020</p> <p>Updated on 31 July 2020, 26 October 2020</p> <p>Currently under review</p>	<ul style="list-style-type: none"> • Fit-checking ensures the respirator fits the user’s face snugly (i.e. creates a seal) to minimise the number of particles that can bypass the filter through gaps between the user’s skin and the respirator seal. • An airtight protective seal is difficult to achieve in the presence of facial hair that underlies the edge of the PFR. The face must be smooth and/or clean-shaven to achieve a good air tight seal. Facial hair should be removed or an alternative type of PFR, such as a powered air-purifying respirator (PAPR) considered (see below). • A range of types and sizes of PFR may need to be fit-checked to find one that achieves a protective seal (i.e. passes fit-check). If a suitable PFR cannot be found an alternative (e.g. PAPR) should be considered. • For further information on fit-testing, see the ICEG guidance on the use of face masks and respirators in the context of COVID-19. <p>Fit-testing, as defined in the Australian/New Zealand Standard 1715: 2009, is a validated method for matching PFRs with an individual’s facial shape, but has not been widely applied in Australia. Despite increased awareness and demand, in the context of COVID-19, it is acknowledged that fit-testing of all health care workers who may need to use a PFR, will be difficult to accomplish due to limited supplies and range of types/sizes available.</p> <p>Note: Fit-testing does not guarantee a respirator will not leak, particularly if a different type or size is used to one previously fit-tested. A repeat fit test is required if a different PFR is utilised. This reinforces the need to fit-check each time a respirator is used.</p>
<p>Clinical Excellence Commission - Application of PPE during COVID-19 Pandemic</p> <p>Version 2.3</p> <p>14 August 2020</p>	<p>Requirements for fit testing</p> <p>A key component of a successful Respiratory Protection Program (RPP) is the assignment of responsibilities for the implementation and coordination of the program. The program should be overseen by a suitably trained person with an understanding of the principles of respiratory protection and the authority to implement the program. This is best led in a collaborative between Workplace Health and Safety (WHS) and Infection Prevention and Control (IPAC). A fit testing program includes the following components.</p> <ul style="list-style-type: none"> • Identification of a dedicated fit testing coordinator or assessor.

Source organisation and title	Recommendations
	<ul style="list-style-type: none"> • Training of an adequate number of internal staff to be competent in fit testing training and assessment. • A process to identify which employees are to be included in a fit testing program including those working in high risk clinical areas, and the priority for training. • Selection of appropriately certified P2/N95 respirators for fit testing which are the same make, model and size of masks that employees are expected to use in practice. • Appropriate storage of disposable respirators according to manufacturer’s specifications (e.g. temperature and humidity) and stock should be controlled and rotated based on a use by date, expiry date or manufactured date. • A procedure and schedule for storing, inspecting and disposing of non-disposable respirators, and cleaning, disinfecting, repairing and maintaining respirators as per manufacturer’s instructions. • Training for staff in understanding transmission risk of airborne pathogens. • Training for staff in the proper use of masks including fit checking. • An evaluation framework to ensure the program responds to the needs of employees based on local risk assessment. • Fit testing assessors should undergo an annual competency assessment. • Documentation system should be established to record health workers’ fit testing results (baseline and ongoing). This should be accessible to both health workers and managers, providing the ability to continually determine the type of individuals fit tested respirator(s), including between LHDs/SHNs. <p>Who should be fit tested? A risk management approach should be applied to ensure that health workers, who routinely and regularly working in areas with a significant risk of exposure to diseases transmitted via the airborne route, are fit tested and are aware of how to perform a fit check. Fit testing will not negate the need for fit checking every time a P2/N95 respirator is put on.</p> <p>Issues to consider when fit testing</p> <ul style="list-style-type: none"> • One mask can’t fit everyone • People experience physiological changes such as weight gain or loss

Source organisation and title	Recommendations
	<ul style="list-style-type: none"> • Health workers with facial hair • Particles and environmental conditions while testing • Accessibility of the exact same make, model, style, and size respirator used to fit test • Stock availability during a pandemic.
<p>Clinical Excellence Commission-Respiratory Protection Program Implementation Resources</p> <p>26 October 2020</p>	<p>Fit Checking</p> <p>Fit checking is required:</p> <ul style="list-style-type: none"> • each time a disposable P2/N95 or reusable respirator is worn • prior to fit testing • for assessment of mask fit in the presence of facial hair • during annual competency or skills assessment • when a HW has difficulties with fit, and needs to have further investigation <p>Fit Testing</p> <ul style="list-style-type: none"> • Priority HWs who cannot participate in fit testing due to medical reasons require a medical certificate to obtain an exemption. Healthcare worker who cannot be fit tested may require redeployment to another clinical area • A consent form (see Appendix C for sample consent form) is required from a HW prior to fit testing <p>The following points should be considered before fit testing:</p> <ul style="list-style-type: none"> • Quantitative fit testing is recommended, e.g. with PortaCount® or AccuFit® machine • Healthcare worker is offered a choice of familiar respirators to try first or based on HealthShare product availability. These respirators will be available in their clinical area (provided or brought by healthcare worker from their clinical area). • PPE used with the respirator includes protective eyewear and any specific headwear to be worn • to ensure that it does not interfere with the fit testing • If healthcare worker requires addition of any protective barriers to protect their skin while wearing the

Source organisation and title	Recommendations
	<ul style="list-style-type: none"> • respiratory, this must be used during the fit testing • Healthcare workers are to complete training and assessment to ensure they are competent in performing fit checks • Healthcare workers are to adjust or modify their hair, facial hair and any adornments to accommodate the fit testing requirements
<p>Australian Department of Health - Information for paramedics and ambulance first responders</p> <p>10 February 2020 Updated on 10 March 2020</p>	<p>Use of PPE in life threatening situations</p> <p>In circumstances where paramedics or ambulance first responders are providing clinical care in life threatening situations (e.g. CPR upon arrival) for a patient with suspected COVID-19, officers may not have sufficient time to adequately apply full airborne precautions. In these circumstances, officers are advised to ensure their own safety including the use of a surgical mask and eye protection as a minimum precaution, or a (fit checked) P2/N95 respirator and eye protection, if available.</p>
<p>Australasian College for Emergency Medicine – Clinical guidelines for the personal protective equipment</p>	<p>Use for clinical care in regions with high community transmission for suspected COVID-19 patients (according to current epidemiological and clinical criteria), and when performing AGPs on suspected or confirmed COVID-19 patients at any community transmission level; for all confirmed COVID-19 patients.</p> <p>We recommend that clinical staff should:</p> <ul style="list-style-type: none"> • Perform procedures in negative-pressure rooms, or an adequately ventilated single room. • Use a particulate respirator[#] such as N95, P2, or equivalent. • Always perform a seal (fit) check of the respirator. • Wear eye protection (goggles) or facial protection (face shield) to avoid contamination of mucous membranes. • Use gloves. • Wear a clean, non-sterile, long-sleeved gown. If gowns are not fluid-resistant, use a waterproof apron for procedures expected to create high volumes of fluid. • Use a hair cover or hood. • Limit the number of people present in the room to the absolute minimum.

Source organisation and title	Recommendations
	<ul style="list-style-type: none"> Practise appropriate donning, doffing and disposal of all PPE and hand hygiene. A trained PPE observer should check technique.
<p>The Australian and New Zealand College of Anaesthetists - ANZCA statement on personal protection equipment during the SARS-CoV-2 pandemic</p> <p>9 April 2020 Updated on 15 May 2020</p>	<p>N95/P2 respirators require formal fit-testing to comply with the Australian and New Zealand standard AS/NZS 1715:2009 and the Australian Government infection prevention and control guidelines.^{7,9} While this may not be attainable in the short-term, the college recommends that organisations commit to providing fit testing for healthcare workers within an ongoing program of testing and healthcare worker education. As the minimum standard, in the first instance, healthcare workers should be fit checked by a suitably trained person. Thereafter, clinicians should ensure they perform a fit check on every occasion in which they don a N95/P2 mask⁷.</p>
<p>Australian Medical Association - Fact sheet regarding COVID-19 testing and initial assessment/care</p> <p>12 March 2020</p>	<p>Contact and airborne precautions should be observed when performing aerosol generating procedures (intubation, bronchoscopy, nasopharyngeal aspirate, induced sputum, bilevel ventilation, CPR), and providing care to patients with severe respiratory symptoms. Contact and airborne precautions require hand hygiene before putting on gown, gloves, eye protection and a (fit checked) P2/N95 respirator.</p>
<p>Victoria State Government- Infection Prevention and Control Guideline</p> <p>Version 3 8 August 2020</p>	<p>Fit testing</p> <p>Fit testing refers to a standardised procedure for testing the seal achieved with an P2/N95 respirator. There are two ways of performing this test; qualitative, using a hood and a fit test solution to determine whether the wearer can smell or taste the airborne substance, or quantitatively, using an instrument to measure the particulate levels inside and outside the respirator to calculate a fit factor. If fit testing is readily available, then it should be considered. However, if it is not reasonably practicable to conduct fit testing due to a shortage of supply of respirators, it may be adequate to implement a program that includes:</p> <ul style="list-style-type: none"> providing appropriate training in the selection, fit and use of a respirator, including fit checking where possible, ensuring a range of respirator types and sizes are available for staff to try on before use

Source organisation and title	Recommendations
	<ul style="list-style-type: none"> • ensuring wearers are clean-shaven where the respirator touches the face • making sure no clothing or jewellery gets between the respirator and the face. <p>A fit-test does not remove the need for a fit check with each mask use.</p> <p>Fit checking</p> <p>Fit checking is the process of ensuring a P2/N95 respirator achieves a good seal once it has been applied and should occur each time a respirator is donned, even if fit testing has previously been undertaken.</p> <p>Healthcare workers must perform fit checks every time they put on a P2/N95 respirator to ensure a facial seal is achieved.</p> <p>Healthcare workers who have facial hair (including 1–2-day stubble) must be aware that an adequate seal cannot be achieved between the P2/N95 respirator and the wearer’s face. The wearer must either shave or seek alternative protection.</p> <p>No clinical activity should be undertaken until a satisfactory fit has been achieved. Fit checks ensure the respirator is sealed over the bridge of the nose and mouth and that there are no gaps between the respirator and face. Healthcare workers must be informed about how to perform a fit check.</p>

Appendix

PubMed search terms (searched on 26 August 2020)

("fit test"[Title/Abstract] OR "fit-test"[Title/Abstract] OR "fit check"[Title/Abstract]) AND ((masks[MeSH Terms]) OR ("respiratory protect"[Title/Abstract] OR "respiratory equip"[Title/Abstract] OR "respirator"[Title/Abstract] OR "mask"[Title/Abstract] OR "n95"[Title/Abstract] OR p2*[Title/Abstract])) AND (2000/1/1:2020/12/31[Date - Publication])

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