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PORTACOUNT® PRO+RESPIRATOR FIT TESTER

HEALTH TECHNOLOGY ASSESSMENT SECTION (MaHTAS)
MEDICAL DEVELOPMENT DIVISION
MINISTRY OF HEALTH MALAYSIA
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DISCLAIMER

Technology review is a brief report, prepared on an urgent basis, which draws on restricted reviews from analysis of pertinent literature, on expert opinion and / or regulatory status where appropriate. It has not been subjected to an external review process. While effort has been made to do so, this document may not fully reflect all scientific research available. Additionally, other relevant scientific findings may have been reported since completion of this review.

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DISCLOSURE

The author of this report has no competing interest in this subject and the preparation of this report is totally funded by the Ministry of Health, Malaysia

EXECUTIVE SUMMARY

Introduction

A fit-test is used to assess whether a specific type, model and size of respirator can adequately fit a specific operator. This is because there are a wide variability in the physical dimensions and characteristics of both human and respirators. The ability of respirator to perform a satisfactory seal between wearer and the contaminated environment may be affected by this variability. In all cases, the individual must be fit-tested in the same model and size of respirator that they will actually use in their work place. These fit tests are available as qualitative and quantitative fit test.

PortaCount® Pro+ Respirator Fit Tester is the respirator fit tester that can quantitatively fit test all types of respirators namely Self- Contained Breathing Apparatus (SCBAs), gas masks, P1, P2, P3 and N95 respirators. This device uses a technology known as condensation nuclei counting (CNC) or condensation particle counting (CPC).

This technology review was conducted following a request by the Director of Hospital Sungai Buloh to assess the safety and efficacy/effectiveness of PortaCount®Pro+ Respirator Fit Tester for fit testing of N95 respirators in healthcare workers.

Objective/aim

The objective of this systematic review was to assess the accuracy, safety and efficacy/effectiveness of PortaCount®Pro+ Respirator Fit Tester for fit testing of N95 respirators in healthcare workers.

Results and conclusions

From the systematic search, ten titles were identified to be possibly related to the topic. Among those titles, only one abstract was included in this review in view of the accuracy of PortaCount® Pro+ Respirator Fit Tester. However, the quality of this study was uncertain as the full text was not retrievable. The practical application of PortaCount® Pro+ Respirator Fit Tester was reported in two studies.

Findings from the review showed that PortaCount Plus with the N95 companion may be suitable for fit assessment as recommended in the Guidance for Industry and FDA Staff Class II Special Controls Guidance Document: Filtering Facepiece Respirator for Use by the General Public in Public Health Medical Emergencies. The PortaCount Respirator Fit Tester has also demonstrated practical application of fit testing using various models of N95 respirators in adult.

Passing a fit test may improve the probability of wearing an individually fit respirator. Hence, it will increase the level of respiratory protection for the health care workers.

Face dimensions, user's training, size and type of respirators are among the possible factors that contribute to the fit of respirators. Individual fit test using different N95 respirators may be needed for each healthcare worker to determine the best fitting respirator based on the factors that affect each individual.

Methods

Electronic databases were searched through the Ovid interface: Ovid MEDLINE® In-process and Other Non-indexed citations and Ovid MEDLINE® 1946 to present, EBM Reviews - Cochrane Central Register of Controlled Trials - December 2014, EBM Reviews - Cochrane Database of Systematic Reviews - 2005 to December 2014, EBM Reviews - Health Technology Assessment – 4th Quarter 2014, EBM Reviews- NHS Economic Evaluation Database 4th Quarter 2014, EBM Reviews- Cochrane Methodology Register 3rd Quarter 2012, EBM Reviews- Database of Abstracts of Review Effects 4th Quarter 2014, EBM Reviews- ACP Journal Club 1991 to December 2014, EMBASE – 1996 to 2015 January 19.

Google was used to search for additional web-based materials and information.. Additional articles were identified from reviewing the references of retrieved articles. Last search was conducted on 10th February 2015.

PORTACOUNT® PRO+RESPIRATOR FIT TESTER MODEL 8038

1. INTRODUCTION

The use of personal protective equipment (PPE) is an approach taken to provide a protection to the related healthcare workers who requires protection from a contaminated environment. Effective protection only achieved through suitable, properly fitted and adequately maintained personal protective equipment. Macintyre et al suggests that rates of infection were double in health care workers wearing medical mask. The rates of clinical respiratory illness(CRI) (3.9% versus 6.7%), Influenza like illness (ILI) (0.3% versus 0.6%), laboratory-confirmed respiratory virus (1.4% versus 2.6%) and influenza (0.3% versus 1%) infection were consistently lower for the N95 respirator group compared to medical masks.¹

A well fitted respirator may provide protection against respiratory hazards such as air-borne microorganisms or viruses. If the facepiece respirator does not seal the air properly, the wearers are exposed to the hazardous or pandemic environment which may be dangerous for their health and lives. Therefore, respirator fit testing is desirable to ensure that the respirator worn provide a minimum fit. However, in countries requiring neither fit test nor inward leakage standards, face and lip lengths and facial size categories may be useful as an alternative tool to select a good fit respirator.²

A fit-test is used to assess whether a specific type, model and size of respirator can adequately fit a specific operator. This is because there are a wide variability in the physical dimensions and characteristics of both human and respirators. The ability of respirator to perform a satisfactory seal between wearer and the contaminated environment may be affected by this variability. In all cases, the individual must be fit-tested in the same model and size of respirator that they intended to use at work. There are two types of fit test; Qualitative or Quantitative Fit testing.³

I. Qualitative Fit testing

Qualitative Fit Test is a pass/fail test relying on the subject's voluntary or involuntary response to a challenge agent for example taste, smell or irritation. There are four types of qualitative fit testing that are currently accepted by OSHA which are Isoamyl Acetate (banana oil), Sodium Saccharin, Bitrex, and Irritant Smoke. The Isoamyl Acetate test uses isoamyl acetate, commonly known as banana oil, as a test agent. If a banana odor is detected during the fit test, the fit is not acceptable. Similarly if sweet test of saccharin or bitter testing test agent, Bitrex is detected by the wearer, the respirators may not fit well. This fit test is limited to fit factor of 100. For irritant smoke test, if enough of the

irritant smoke leaks into the mask it will result in a reaction such as coughing or watery eyes.

II. Quantitative fit testing

Quantitative fit testing measures the challenge agent leakage into the respirator without dependence on a test subject's voluntary or involuntary response to the challenge agent. Several quantitative fit tests are available for respirator fit testing. These include ambient aerosol challenge systems, aerosol generator or booth systems, and controlled negative pressure systems.

a) Ambient aerosol challenge systems

This method measures inner and outer aerosol concentration of the respirator and calculated to the fit factor just like other quantitative methods. Ambient aerosol fit testers use a technology known as condensation nuclei counting (CNC) or condensation particle counting (CPC).

b) Aerosol generator or booth systems

The aerosol generator or booth systems consist of an aerosol generator, a booth or chamber, and a photometer based aerosol detector. The aerosol generator produces a high concentration of challenge aerosol (usually corn oil) that is injected into a booth or chamber used to contain the aerosol. The test subject stands inside the chamber and performs a series of exercises as the instrument samples how much challenge agent leaks into the respirator.

c) Controlled negative pressure systems

This method uses special adapters that allow the breathing air supply to be temporarily cut off to replace the filter cartridges. The instrument pulls a fixed vacuum on the mask and measures the airflow (leak rate) needed to maintain the vacuum. However, this method is not suitable for filtering facepiece respirators.

This technology review was conducted following a request by the Director of Hospital Sungai Buloh to assess the accuracy, safety and efficacy/effectiveness of PortaCount® Pro+ Respirator Fit Tester for fit testing of N95 respirators in healthcare workers.

2. OBJECTIVE / AIM

The objective of this systematic review was to assess the accuracy, safety and efficacy/effectiveness of PortaCount® Pro+ Respirator Fit Tester for fit testing of N95 respirators in healthcare workers.

3. TECHNICAL FEATURES

PortaCount® Pro+ Respirator Fit Tester (Figure 1) is the respirator fit tester that can quantitatively fit test all types of respirators namely Self-contained breathing apparatus (SCBAs), gas masks, P1, P2, P3 and N95 respirators. It uses a technology known as condensation nuclei counting (CNC).⁴⁻⁵



Figure 1: PortaCount® Pro+ Respirator Fit Tester Model 8038⁴

In comparison to other respirator fit testing, PortaCount® Pro+ Respirator Fit Tester measures the fit while the user simultaneously performs a series of designed activities such as moving, breathing and talking exercises to simulate the movements made in the workplace. The technical specifications of PortaCount® Pro+ Respirator Fit Tester for fit testing of N95 respirators were described as Table 1.⁴

Table 1: Technical specification of PortaCount® Pro+ Respirator Fit Tester

Technical specification	Description
Power	Autosensing 100 to 250VAC, 50 to 60 Hz
Dimension	17cm x 22cm x 24cm
Weight (with standard accessory and case)	8.2kg
Flow rate	Sample: 350 cm ³ /min Total: 1000 cm ³ /min (nominal)
Fit factor measurement	(C _{out} /C _{in})
Fit factor range	1 to > 10,000 1 to 200 for N95 masks
Fit factor accuracy	± 10% of reading
Pass or fail setting	User selectable: 0 to 10,000
Temperature range	Operation: (0-38°C) Storage: (-40 to 70°C)
Alcohol (99.5% + reagent grade isopropyl)	Hours per change: 6 hours at 21°C
Factory recalibration interval	One year

The operation for PortaCount® Pro+ Respirator Fit Tester used the technology of condensation nuclei counting (CNC) or condensation particle counting (CPC). The ambient particles are mixed with alcohol vapours which will condense the particles. Subsequently, the particles will become large and counted through the fit tester. Then, the fit factor is calculated by dividing the amount of particles outside and inside the respirators. The difference of PortaCount® Pro+ Respirator Fit Tester Model 8038 in comparison to other models is that it can eliminate the sizes or particles allowable to penetrate the N95 respirators filters.

Among the advantages of PortaCount® Pro+ Respirator Fit Tester for fit testing N95 respirators are there was no influence from the wearer and the result was presented numerically.⁵ Passing a fit test with the PortaCount® Pro+ Respirator Fit Tester will also provides hardcopy documentation that the person has learned how to don the mask properly and has been issued a mask that is properly sized to achieve rated protection levels.

Therefore, the healthcare workers and their supervisors may know the respirator that offers the best fit possible for them. Additionally, PortaCount® Respirator Fit Tester has been used in the evaluation of 'side by side' probe mounting which is used to extract an air sample from inside of the respirator facepiece.⁶ Among the disadvantage of this technology is that it cannot distinguish between particles that have leaked around the face seal of the respirator and those that have been generated by the wearer.⁷

4. METHODS

4.1. Searching

Electronic databases were searched through the Ovid interface: Ovid MEDLINE® In-process and Other Non-indexed citations and Ovid MEDLINE® 1946 to present, EBM Reviews - Cochrane Central Register of Controlled Trials - December 2014, EBM Reviews - Cochrane Database of Systematic Reviews - 2005 to December 2014, EBM Reviews - Health Technology Assessment – 4th Quarter 2014, EBM Reviews-NHS Economic Evaluation Database 4th Quarter 2014, EBM Reviews- Cochrane Methodology Register 3rd Quarter 2012, EBM Reviews- Database of Abstracts of Review Effects 4th Quarter 2014, EBM Reviews- ACP Journal Club 1991 to December 2014 and EMBASE – 1996 to 2015 January 19.

Google was used to search for additional web-based materials and information. No other limits were applied. Additional articles were identified from reviewing the references of retrieved articles. Last search was conducted on 20th January 2015. Appendix 1 showed the detailed search strategies.

4.2. Selection

A reviewer screened the titles and abstracts against the inclusion and exclusion criteria and then evaluated the selected full text articles for final article selection.

The inclusion and exclusion criteria were:

Inclusion criteria

Population	Health care workers
Interventions	PortaCount®Pro+ Respirator Fit Tester
Comparators	Qualitative fit test / Quantitative fit test
Outcomes	Accuracy of the particle counting
Study design	Health Technology Assessment, Systematic Reviews,

	Randomised Controlled Trial (RCT), Non Randomised Controlled Trial, Cohort studies, Cross sectional studies, Case Series, Case Reports
Language	English full text articles

Exclusion criteria

Study design	Studies conducted in animals, narrative reviews, commentary. letters
Language	Non English full text articles

Relevant articles were critically appraised using Critical Appraisal Skills Programme (CASP) and graded according to US/Canadian preventive services task force (Appendix 2). Data were extracted and summarised in evidence table as in Appendix 3.

5. RESULTS AND DISCUSSION

From the systematic search, ten titles were identified to be possibly related to the topic. Among those titles, only one abstract was included in this review in view of the accuracy of PortaCount® Pro+ Respirator Fit Tester. However, the quality of this study was ascertained as the full text was not retrievable. The practical application of PortaCount® Pro+ Respirator Fit Tester was reported in two studies.

5.1. SAFETY

There was no information on CE Mark for this device. According to Major Requirements of United States Occupational Safety and Health Administration (OSHA)'s Respiratory Protection Standard 29 CFR 1910.134, a fit testing is required prior to respirator's use and whenever different respirators are used by the workers using an acceptable protocol either as qualitative or quantitative test. This document also stated that training and important information must be adequately provided to the respirator users.⁸ Frequency of the training may be determined by the employers such as once a year.

Similarly, the United States Food and Drug Administration (USFDA) recommend the fit assessment in the Guidance for Industry and FDA Staff Class II Special Controls Guidance Document: Filtering Facepiece Respirator for Use by the General Public in Public Health Medical

Emergencies and the use of PortaCount Plus with the N95 companion may be suitable for this assessment.⁹

5.2. ACCURACY

Based on an abstract by Coffey CC et al. the PortaCount fit tester has a good coefficient determination, R^2 of 0.78 with the end-exhaled air analysis (Freon-13). A coefficient of 1 is considered as a perfect match while 0.5 is considered as poor.¹⁰

5.2. EFFICACY/EFFECTIVENESS

The practical application of the PortaCount® as a fit tester was demonstrated in several studies using the fit-test passing rate. Based on this passing rate, the employers will be able to select the most suitable filtering face piece respirators that would likely fit the greatest percentage of their employees.

A study by Yu Y et al. was conducted to investigate the fit of ten models of N95 filtering-face piece respirators (FFR) used in China measured using the TSI PortaCount Plus. Fifty adults donned 10 models of FFR with three replication tests for each of the model. The overall passing rates for all ten model was 7.8% with the highest passing rate of 44.7% for one model (D1), while none passed the tests when used three other models (C1,C3,C4). Furthermore, there were more than half of the participants (54%) who did not pass the fit tests using all models.^{11Level II-3}

The author also reported the effect of training on respirator fit as there was a statistically significant different of geometric mean fit factors between trained and untrained group for two models of selected respirators ($p < 0.05$). There was also different in mean geometric fit factors that have been reported among various face dimensions indicating that adults with certain face dimension in China may have difficulties to find appropriate respirator that fit them. The findings also indicated that the cup respirator fit better for males and the folding respirator fit better for females. Additionally, the author suggested that the low fit factors may also contributed by the size of respirators.^{11Level II-3}

Similarly, Coffey CC et al. also conducted a study to assess the effect of fit testing on the level of protection of 25 subjects with various face sizes. For fit testing, eighteen N95 respirators were tested using both qualitative and quantitative tests. There were some models with great variations of passing rate depending upon the fit tests used. The findings showed that N95 respirator from (North Safety products, Cranston, RI) had a passing rate of 0.55 with the qualitative fit test but none of the participants pass the

quantitative fit test using TSI PortaCount. These findings suggested that passing a qualitative fit test may not necessarily result in adequate protection of the healthcare workers. This study also assessed the level of protection provided by eighteen models of N95 FFR using various techniques; 5th percentile simulated workplace protection factor (SWPF) values, shift average SWPF, h-values and assignment error.^{12 Level II-3}

5.3. DIRECT COST

PortaCount® Pro+ Respirator Fit Tester for fit testing of N95 respirators is priced according to the United States Dollar (USD) with an estimated price in Malaysia between RM 68,000 to RM 70,000. The estimated cost includes an initial training from a certified trainer, a set of essential accessories and computer software. An annual cost will incur for the factory recalibration as notified by the manufacturer. According to the information from the distributor, the life span of this device may achieve 10 years with proper handling and adequate maintenance.

5.4 LIMITATIONS

This technology review has several limitations. The methodological quality of the included study using CASP assessment tool was not possible as the full text article was not retrievable. Although there was no restriction in language during the search but only English articles were included in this report. In addition, the selection of studies was done by one reviewer.

6.0 CONCLUSION

Findings from the review showed that PortaCount Plus with the N95 companion may be suitable for fit assessment as recommended in the Guidance for Industry and FDA Staff Class II Special Controls Guidance Document: Filtering Facepiece Respirator for Use by the General Public in Public Health Medical Emergencies. The PortaCount Respirator Fit Tester has also demonstrated practical application of fit testing using various models of N95 respirators in adult.

Passing a fit test may improve the probability of wearing an individually fit respirator. Hence, it will increase the level of respiratory protection for the health care workers. Face dimensions, user's training, size and type of respirators are among the possible factors that contribute to the fit of respirators. Individual fit test using different N95 respirators may be needed for each healthcare worker to determine the best fitting respirator based on the factors that affect each individual.

7.0 REFERENCES

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8.0 APPENDIX

8.1. Appendix 1: LITERATURE SEARCH STRATEGY

Ovid MEDLINE® In-process & Other Non-Indexed citations and OvidMEDLINE® 1946 to present

1. ambient aerosol fit-test instruments or quantitative fit-testing and portacount pro+ respirator fit tester {Including Related Terms}

- *Search terms used:*

- 8038
- 8038s
- ambient
- ambients
- aerosol
- aerosoled
- aerosoling
- aerosols
- volatile solvent aerosol propellant
- fit test
- instruments
- instrument
- musical instrument
- clinical instrument
- instrument device
- quantitative
- fit testing
- fit-testings
- portacount
- portacounts
- pro+
- pro
- pros
- proline
- prolines
- l proline
- respirator
- respirators
- ventilator
- ventilators
- respirator device
- ventilators mechanical
- ventilator pulmonary
- pulmonary ventilators
- pulmonary ventilator
- mechanical ventilators
- mechanical ventilator
- fit

- convulsions
- convulsion
- fitting
- looks well
- state of being healthy
- fit and well
- fits
- tester
- testers
- tester device
- model
- models biological
- models biologic
- modeling system
- model system
- model biological
- model biologic
- biological models
- biological model
- biologic models
- biologic model
- models
- study models

OTHER DATABASES	
EBM Reviews - Cochrane Central Register of Controlled Trials	} Same MeSH, keywords, limits used as per MEDLINE search
EBM Reviews - Cochrane database of systematic reviews	
EBM Reviews - Health Technology Assessment	
EBM Reviews - ACP Journal Club	
EBM Reviews – Database of Abstracts of Reviews Effects	
EBM Reviews – Cochrane Methodology Register	
EBM Reviews – NHS Economic Evaluation Database	
EMBASE	

8.2. Appendix 2

DESIGNATION OF LEVELS OF EVIDENCE

- I Evidence obtained from at least one properly designed randomized controlled trial.
- II-1 Evidence obtained from well-designed controlled trials without randomization.
- II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group.
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.
- III Opinions or respected authorities, based on clinical experience; descriptive studies and case reports; or reports of expert committees.

SOURCE: US/CANADIAN PREVENTIVE SERVICES TASK FORCE (Harris S2001)

Evidence Table : Efficacy/Effectiveness
Question : Is PortaCount® Pro+ Respirator Fit Tester Model 8038 effective for fit testing of N95 masks on hospital staff?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
<p>Yu Y, Jiang L, Zhuang Z et al. (2014). Fitting Characteristics of N95 Filtering-Facepiece Respirators Used Widely on China. PLoS ONE 9(1):e8529. doi:10.1371/journal.pone.0085299.</p>	<p>Cross sectional</p>	<p>II-3</p>	<p>50 adult participants were selected and donned 10 common models of N95 filtering-facepiece respirators (FFR), (A1,A2,B1,B2, C1,C2,C3,C4, D1,D2)</p>	<p>TSI Porta Count Plus model 8020</p>	<p>-</p>	<p>-</p>	<p>Overall passing rates for all 10 models=7.8% with the highest passing rate was 44.7% for one model (D1), while none passed the tests when used 3 other models.</p> <p>There were more than half of the participants (54%) who did not pass the fit tests using all models.</p>	<p>-</p>

Evidence Table : Efficacy/effectiveness

Question : Is PortaCount® Pro+ Respirator Fit Tester Model 8038 effective for fit testing of N95 masks on hospital staff?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
Coffey CC, Lawrence RB., Campbell DL., et al.(2004). Fitting Characteristics of Eighteen N95 Filtering-Facepiece Respirators. Journal of Occupational and Environmental Hygiene.1:262-271.	Cross sectional	II-3	A panel of 25 subjects with various face sizes donned 18 models of N95 filtering-facepiece respirators	TSI PortaCount Plus with the N95 Companion, PortaCount Plus with filter penetration, Bitrex, Saccharin, and generated aerosol	Without fit testing	-	<p>The percentage of the subjects passing the fit tests varied widely.</p> <p>Some models yielded great variations of passing rate depending upon the fit tests used.A N95 respirator from North Safety products, Cranston, RI had a passing rate of 0.55 with the qualitative fit test but none pass the quantitative fit test.</p> <p>4 techniques or procedures to determine filtering-facepiece respirator performance:</p> <ol style="list-style-type: none"> 1) Distribution of 5th percentile SWPF values 2) Shift average SWPF 3) h-values 4) Assignment error 	-