THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

World Health Organization Collaborating Centre for Community Health Services
世界衛生組織社區健康服務合作中心

Chinese specific-N95 respirators for the coming and future respiratory infectious outbreak: Development, licensing, patent and manufacturing

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Outlines

A. Background and current problems

B. Initiatives of N95 development

- Pre-test results

C. Patent and Licensing

D. Manufacturing

E. Impacts

Background

- Worldwide outbreaks of different infectious respiratory diseases[1-4]
  - Alert the significance of respiratory protection
  - N95 respirator is recommended in some clinical settings[5,6]

- N95 Respirator as protection
  - A kind of effective nonpharmaceutical measure to limit its spread in hospitals
  - Is a half-face filtering tight-fitting mask, which concerns the design of masks and the facial anthropometries of users
    - Donning/Wearing skills of users (can be trained) (Lam et al., 2011a, 2016)
    - Fit or unfit (can be assessed by quantitative fit testing) (Lam et al., 2011a, 2011b, 2016)
    - Usability (self-reporting, affecting compliance and usage)
  - It was compulsory used in some infectious environments or when performing some procedure, namely resuscitation and suctioning.

Difference between N95 respirator and facemask

Understanding the Difference

	 Surgical Mask	 N95 Respirator
Testing and Approval	Cleared by the U.S. Food and Drug Administration (FDA)	Evaluated, tested, and approved by NIOSH as per the requirements in 42 CFR Part 84
Intended Use and Purpose	Fluid resistant and provides the wearer protection against large droplets, splashes, or sprays of bodily or other hazardous fluids. Protects the patient from the wearer's respiratory emissions.	Reduces wearer's exposure to particles including small particle aerosols and large droplets (only non-oil aerosols).
Face Seal Fit	Loose-fitting	Tight-fitting
Fit Testing Requirement	No	Yes
User Seal Check Requirement	No	Yes. Required each time the respirator is donned (put on)

Like Aerosol generating procedure

Non-pandemic setting

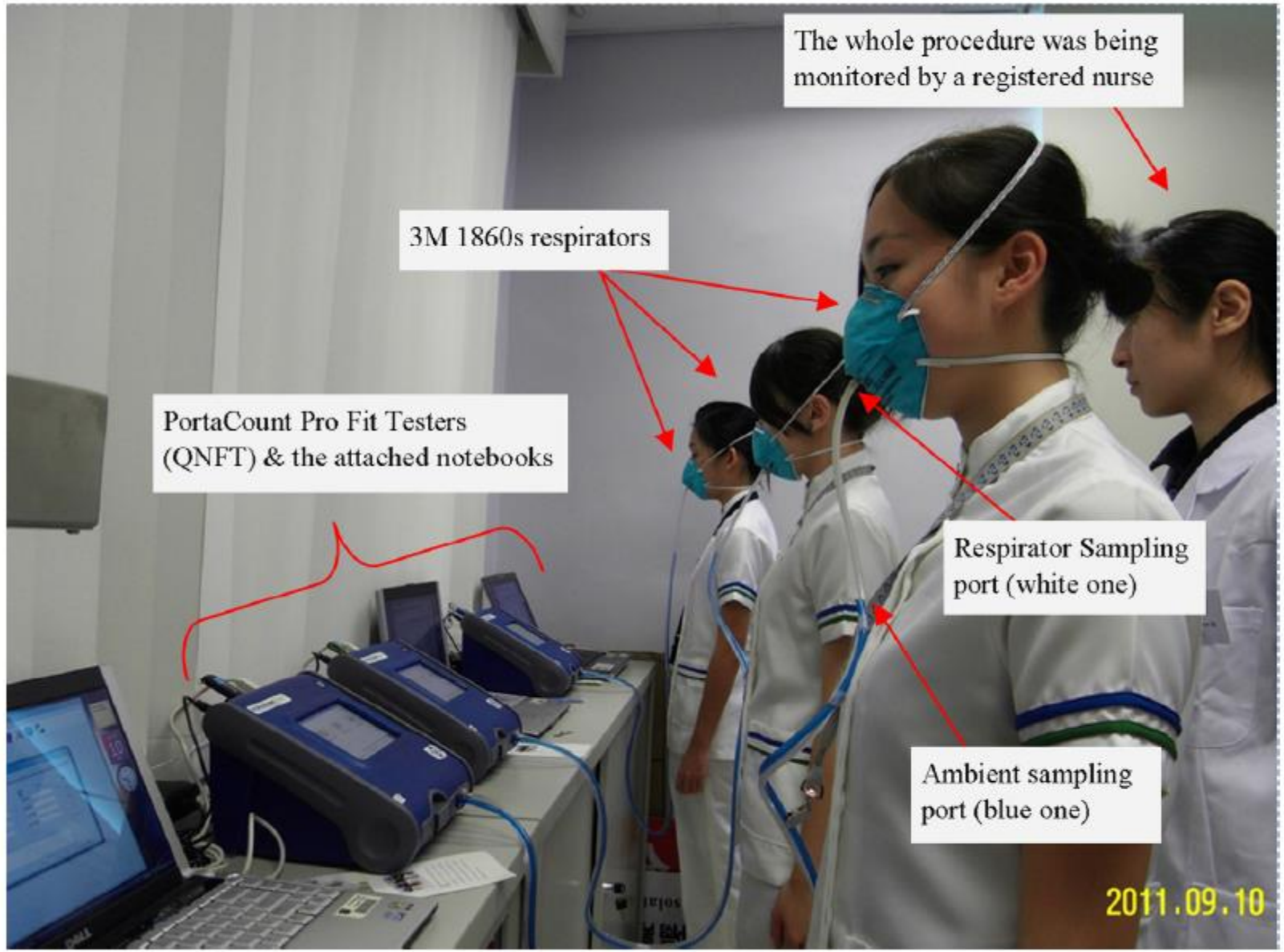


Fig 2. Fit tester system, tubing connection, and respirator. *QNFT*, quantitative fit testing.

Local context: Use of N95 respirators

- Private hospitals and the hospitals under hospital authority regularly provided two to three major types of N95 respirators for all healthcare workers in workplace, including in suctioning room or on resuscitation trolley (Hospital Authority, 2017).
  - Cup-shaped 3M 1860 (regular / small)
  - 3-panel designed 3M 1870+ (regular)
  - Pouch-type Kimberly-Clark 46827 (discontinued after 2016, only some stock now, Lam et al., 2011)
- Manufacturers claimed that all 3M respirators are 86-100% fit to people (3M, 2015).
- However, their performance when donned for Chinese people was suboptimal on protection and comfort, compared with that for the West.

Literature review- fit rate

- Studies from **West** indicated a high fit rate of respirators
  - 3M 1870 fit rate = 93.8-100% (for the age of 19-71 Canadian healthcare workers, N = 1271) (McMahon et al., 2008)
  - TC 84A-2630 and TC 84A-0006 (i.e., 3M 1860) fit rate = 90-98% for American healthcare workers (N = 1887) (Lee, Slavcev, & Nicas, 2004)

- **Local** studies on Chinese indicated a medium fit rate only
  - ICU staff: N95 respirator may fit only 55-69% ICU staff (Derrick, Chan, Gomersall, & Lui, 2005)
  - Nursing students: 3M 1860s & 1862 57.4%-61.3% (N = 204) (Lam, Lee, Yau, & Charm, 2011); 59%–65% (N = 349) (Lam, Lee, Lee, Wong, & Lee, 2011).

- Conventional respirators did not fit Chinese well (before the COVID-19).

Different problems in 2020 and 2021

Suen et al., 2020

- In 2020:
  - Shortage of N95 respirators.
    - Import restriction of 3M N95 model.
  - Many claimed N95 respirators are not up to standard, some are fake.

NASK M0011

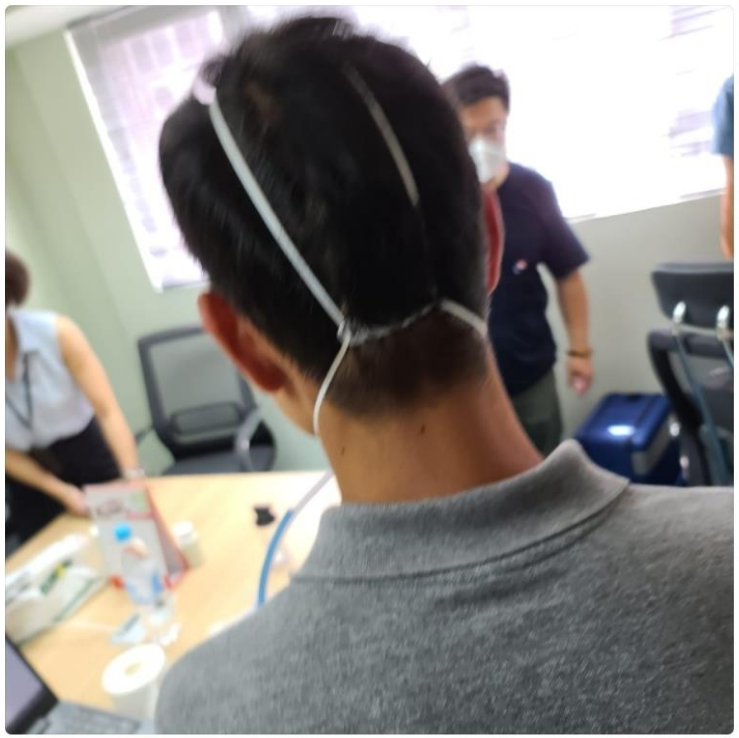
- In 2021:
  - The sole supplier of NASK M0011 **earloop design with clips**.
    1. Which the design is **different from** the published article (Suen et al., 2020).
    2. Non-standardized donning, manipulated by human factor
    3. Frequent changes of the strength of strap…
    4. Complaint of pressure sore and injury on ear, chin and head.

Non-standardized donning

Standard two clips method

one clip method for increasing the chance of pass

Photo from one of HA hospitals



see top & bottom hooks, pulling or extending both ear loops for better sealing 22:10

Square method for increasing the chance of pass

Official complaint letter from a nursing association to the Hospital Authority

香港護士協會 ASSOCIATION OF HONG KONG NURSING STAFF
九龍佐敦白加士街 25-27 號慶雲商業大廈三樓 3/F., Hing Wan Commercial Building, 25-27 Parkes Street, Jordan, Kowloon.
總機電話及二十四小時傳真熱線： 2314 6900 Website : http://www.nurse.org.hk E-mail : info@nurse.org.hk

親子天地	福利部	電器部	保險部	教育部	會籍部	勞資及公共關係部
電話：2314-6925/6945	2314-6910/6961	2314-6924/6941	2314-6912/6944	2314-6911/6977	2314-6927/6915	2314-6962
傳真：3521-0321	3521-0434	3521-0434	3521-1540	3521-1540	3521-1540	2314-1997

中央通訊：1/21

反映 NASK 納米纖維智能口罩的問題和使用實況

本會接獲同業就醫管局現時使用的「NASK 納米纖維智能口罩」的求助個案，同業指出該款口罩在面型配合測試、實際使用和質量均出現問題，有關的情況如下:

1) 面型配合測試的工作並不嚴謹，其中更要求同業減低進行護理程序時的動作幅度，以防「漏氣」
2) 配戴時需配合耳帶扣，甚為不便
3) 長時間配戴時會出現壓痕，而且更會出現痛楚和磨損的情況
4) 配戴和解除裝備時曾出現耳帶斷線的質量問題

Increasing the fit rate by compromising the usability

What is the criteria of a good N95 respirator

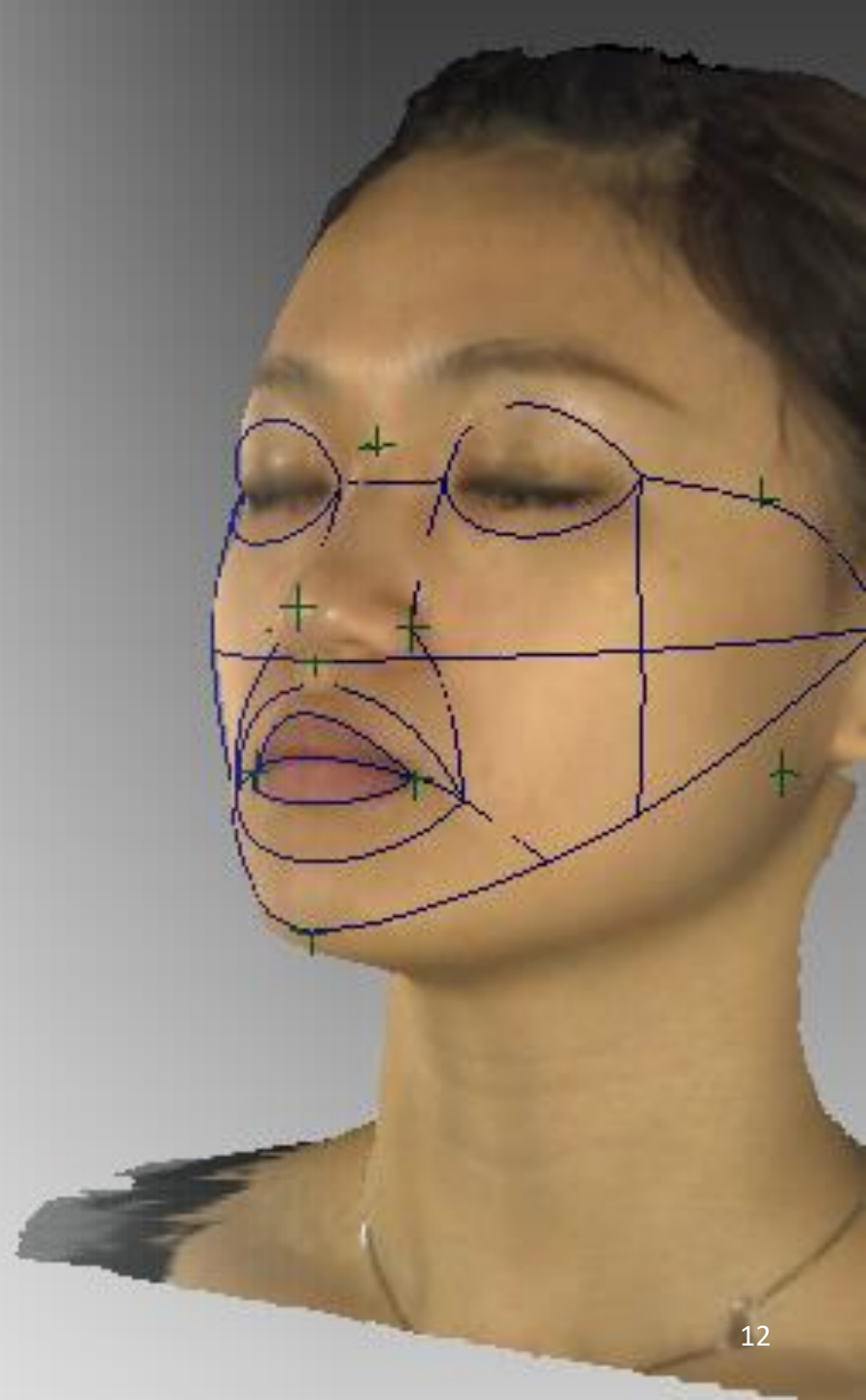
- High fit rate to the population of wearer
  - To obtain using a very tight strap to reduce the face seal leakage…
- High usability (e.g., breathability, tightness, comfort and prolonged usage) to the population of wearer
  - To obtain using a breathable material, optimal tightness, nose foam…

- A good respirator should be the balance between fit rate and usability.

Initiatives of N95 respirator development

- Development:

1. Shape and size:
   - Research on 700 data (3D image) of facial anthropometrics of nurses (Lui et al., 2012)
2. Head strap:
   - Uneasy to be displaced
   - High elasticity
   - Adjustable if possible



N95 Development

- Development:

1. Shape and size:
   - Select KN95 and KF94 shape as first draft for revising
2. Head strap:
   - Uneasy to be displaced: PVC is stickier to hair
   - High elasticity: PVC synthetic rubber, optimal elastic recovery and tensile strength, tear strength, fatigue life…
   - Adjustable: It is a one-off disposable device, need a simple but effective design. (Explain with sample…)

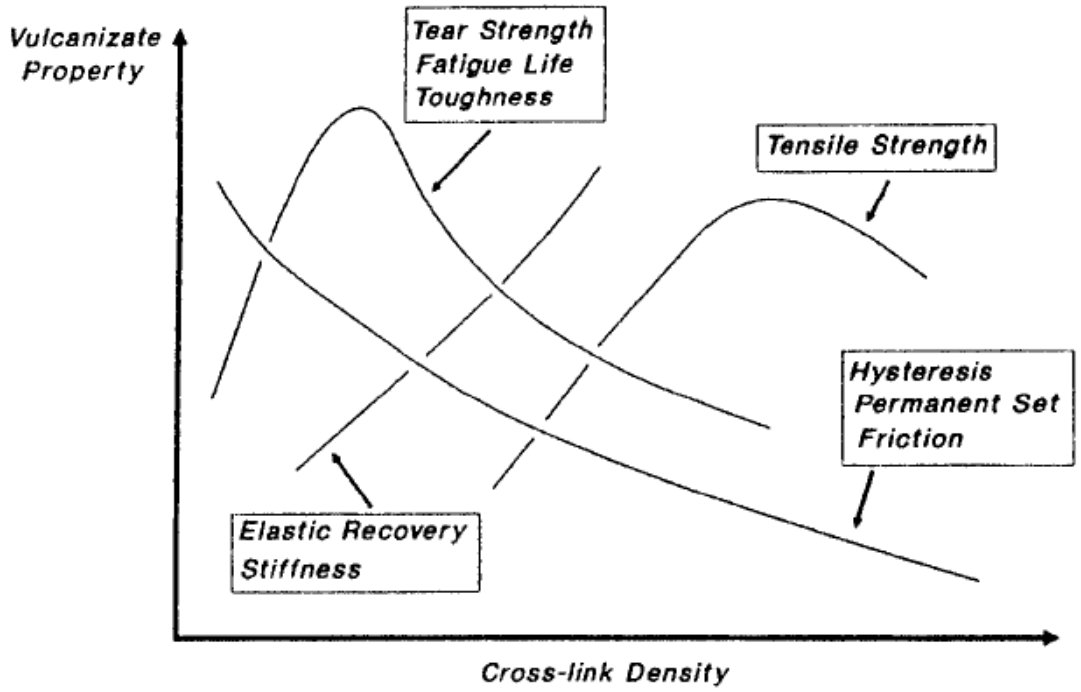


FIGURE 33.1 Vulcanizate properties as a function of the extent of vulcanization. (*Eirich and Coran.*[3])

(Schaefer, 2018)
https://www.mtec.or.th/wp-content/uploads/2018/04/mechanical-properties_rubber.pdf


V9580+ modified from KN95 model
V8380+ modified from KF94 model
VANNEX
SHOT ON MI 8 PRO
AI DUAL CAMERA
2021/1

Preliminary fit rate on Healthcare professionals without adjusting the head strap

Table 1. Characteristics of facial anthropometries and grouping

Characteristics		Face width (cm)	Face length (cm)	Face area (cm^2)
Minimum		10.30	9.70	107.12
Maximum		18.60	13.70	203.50
Range		8.30	4.00	96.38
Mean (SD)		13.248 (0.94)	11.322 (0.72)	150.220 (16.54)
First 1/3 percentiles		12.83	10.97	137.64
Second 1/3 percentiles		13.52	11.58	155.65

Table 2. Fit test passing rate on three groups with comparing to previous 3M models.

Fit test passing rate		Small face size (n = 117)	Medium face size (n = 117)	Large face size (n = 116)
Face area (cm^2)		107.12-137.64	137.64-155.65	155.66-203.50
V8380+		71.2-76.9%	71.8-73.5%	57.3-62.1%
V9580+		88.2-94.1%	80.6-84.4%	80.6-83.9%
3M 3-panel model comparable to V8380+		53.1-59.0%[1,4,5]		
3M Cup shape model comparable to V9580+		61.3-65.0%[1,4,5]		

[4,5]refer to the below publication on fit test for Chinese healthcare workers

Usability comparison between two respirators

- Samples: 26 healthcare workers (18 female) donned for 7 days, 6 hours per shift.

Table 4. Usability (2-3 hours of donning) of two new models with comparison of NASK M0011 mask

	請於以下每項圈上你的選擇*	NASK M0011 (n = 26)	V8380+ (n = 26)
1.1	這口罩使我感到悶熱 (feeling of heat)	4.20	4.00
1.2	這口罩影響我呼吸 (affecting breathability)	3.80	4.33
1.3	這口罩令我面部繃緊 (feeling tightness)	2.60	4.67
1.4	這口罩影響我說話 (difficult in talking)	4.20	4.33
1.5	這口罩使我皮膚敏感 (facial itchiness)	5.40	4.67
1.6	這口罩容易移位 (ease of being displaced)	4.40	4.67
1.7	這口罩令耳部位置不適 (discomfort on ear lobe)	2.20	4.67
1.8	這口罩可以長時間使用 (can use in long duration)^^	4.80	3.00
1.9	這口罩降低我工作效率 (lowering my working efficiency)	4.00	4.67
1.10	這口罩對眼鏡/眼罩造成霧氣 (若適用) (mist over glasses)	3.20	4.33
1.11	這口罩的整體舒適度 (overall comfort)^^	3.40	2.33

Samples: 26 healthcare workers (18 female) donned for 7 days, 6 hours per shift.
*Rating on 6 point scale (range 1= very disagree – 6 = very agree): higher score, better usability
^^ negatively worded items
Yellow highlights the best one with great difference (>0.2)

Preliminary fit rate on Healthcare professionals with adjusting the head strap

基督教靈實協會 HAVEN OF HOPE CHRISTIAN SERVICE

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RESPECTING LIFE • IMPACTING LIFE

To: Prof. Jin-Guang Teng
The President,
The Hong Kong Polytechnic University. (president.office@polyu.edu.hk)

Attn: Ms. Eunice Cheng
Interim Director of Communications and Public Affairs,
The Hong Kong Polytechnic University. (eunice.ol.cheng@polyu.edu.hk)

Letter of appreciation to School of Nursing, The Hong Kong Polytechnic University

Dear Prof. Jin-Guang Teng,

Haven of Hope Sister Annie Skau Holistic Care Centre is a non-profit, self-financing nursing home, providing holistic care integrating medical, nursing, rehabilitation and pastoral care services to the frail elders, chronically ill and late-stage cancer patients. Due to the COVID-19 outbreak, we continually purchased face masks for our staff and service users to maintain the above operation and services. However, we came across with many potential fake and low-quality surgical masks that posed safety concerns to our frontline healthcare professionals as well as our clients.

Preliminary fit rate on Healthcare professionals
with adjusting the head strap

Due to the 4th waves of COVID-19 outbreaks in Hong Kong, we seek the help for Dr. Simon Ching Lam and his team (Squina International Centre for Infection Control, School of Nursing) again performing N95 fit testing for all our frontline staff. This was important to us because we need to perform some aerosol generating procedure for our residents.

With a total of five full days works in our centre, all our 104 frontline staff completed the N95 fit testing. Dr. Lam also recommended Vannex N95 surgical particulate respirators (developed by your university) to us. The model of V8380+ and V9580+ obtained a very good fit rate, that is 87% to 88%. All staff can pass the fit testing with both or either one of these respirators, which facilitated our stock and daily operation.

靈實司務道寧養院 Haven of Hope Sister Annie Skau Holistic Care Centre
香港新界將軍澳靈實路十九至二十一號 19 - 21 Haven of Hope Road, Tseung Kwan O, New Territories, Hong Kong
服務熱線 Service Hotline: (852) 2703 3000 | 傳真 Fax: (852) 2703 5575 | 電郵 Email: sashcc@hohcs.org.hk
香港公益金 The Community Chest 會員機構
根據《公司條例》(第622章)，基督教靈實協會為一所擔保有限公司。
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More important, the usability of these respirators (e.g., optimal tightness, comfort level and prolonged usage) were all satisfactory and better than any conventional model. We appreciate the development of these N95 respirators for the benefit of mankind as well as infection control and prevention in the current and future respiratory infectious diseases.

We would like to express our appreciation to the professional works provided by Dr. Lam and the development of N95 respirators by the PolyU during the COVID-19 pandemics. Please feel free to contact me at 2703 3007 if there is any enquires. Thank you very much.

Best regards,

Application of Patent

香港特別行政區政府知識產權署專利註冊處

Patents Registry, Intellectual Property Department

The Government of the Hong Kong Special Administrative Region

知識產權署
Intellectual Property Department

In reply please quote this ref.: 32020021992.3

Your ref.: JHC/U20119HK00

Tel.: 2961 6898
Fax.: 2838 6315

eMode

14 December, 2020

SPRUSON & FERGUSON (HONG KONG) LIMITED
5001 Hopewell Centre
183 Queen's Road East, Wan Chai
HONG KONG

Application for Grant of a Short-term Patent
Under Application No. 32020021992.3

We refer to your application for a short-term patent lodged on 11 December, 2020.

RESPIRATOR WITH ADJUSTABLE STRAPS

具有可調節帶的呼吸器

TECHNICAL FIELD

[0001] The present disclosure generally relates to a respirator or a face mask. More particularly, the present disclosure relates to a respirator with adjustable straps that can achieve tight-fitting on most wearers.

BACKGROUND

[0002] Airborne transmission is generally a disease transmission of various viral diseases

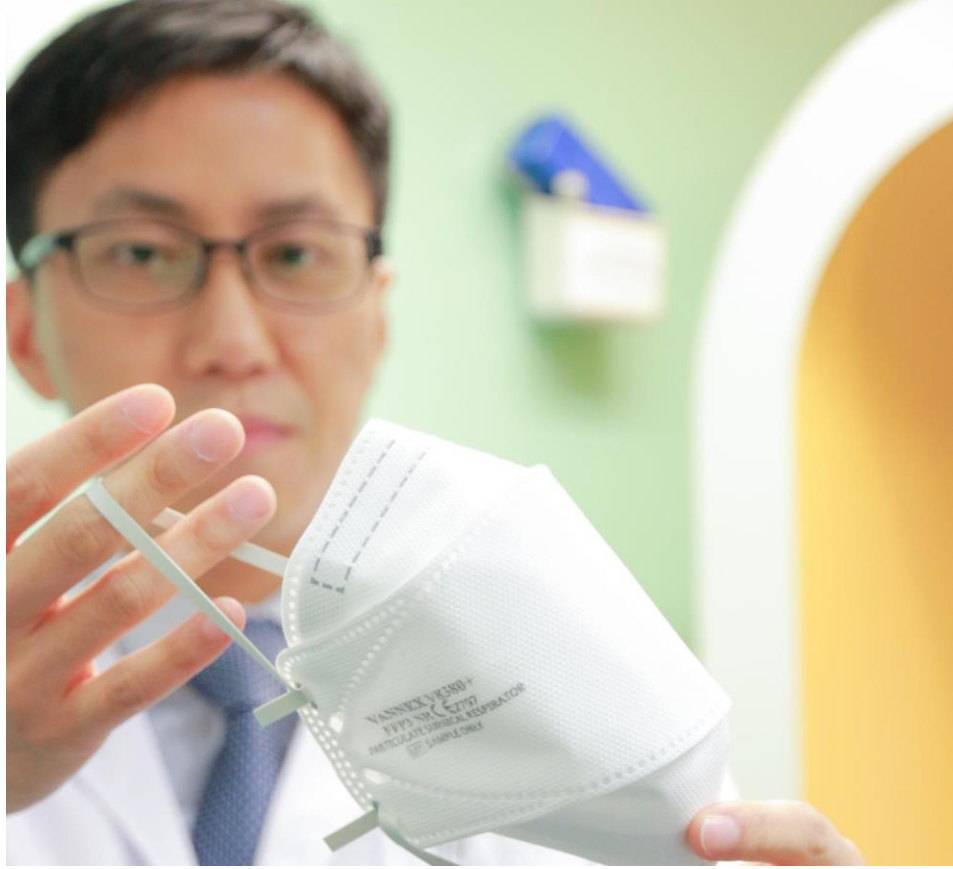
Approved licensing agreement

Collaboration with industrial partners

- CONFIDENTIAL…
- After checking the quality of clean room, machine…
- But remember to sign a MOU, at least…

Impacts

- We have provided samples of the new respirators to the Hospital Authority (HA) Head Office, hospitals under HA, and some private hospitals for trial and examination.
- Several organizations are adopted now.
- The new respirators will certainly play an important role in protecting ten thousands of our healthcare professionals in hospitals and clinics, as well as healthcare workers in the community in Hong Kong.



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Thank you for your time

Key references:

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