東華學院
TUNG WAH COLLEGE

29 September 2021

To whom it may concern,

A Public Clarification - an Experimental Study on the Mask Fit and Usability of Nanofibre N95 Filtering Facepiece Respirators in 2015

1. On 28 February 2021, MingPao published a special feature (特稿) on an experimental study ("**the Study**") conducted by Professor Lorna Suen ("**Prof. Suen**") and her team at the Hong Kong Polytechnic University ("**PolyU**") before she joined Tung Wah College as the Dean and Professor of the School of Nursing. The full title of the Study is "**Comparison of respiratory protection and comfort of different types of N95 masks during nursing procedure in a simulated clinical setting"**.

2. More specifically and as shall be addressed in detail below, the said Study commenced in the year of 2015 and was aimed to "evaluate the mask fit and usability of the best-fitting "*3M N95*" filtering facepiece respirators (masks) and the "*nanofibre N95*" filtering facepiece respirators before and after nursing procedures". The physical properties of these test subjects were also examined. The Study was completed on 31 July 2017 and the paper titled "**mask fit and usability of traditional and nanofibre N95 filtering facepiece respirators before and after nursing procedures"** ("**the Article**") was made available online on 20 September 2019 which was later published in the year of 2020.

3. The said MingPao feature ("**the Feature**") reported on the complaints received by the Hospital Authority ("**HA**") amidst the outbreak of COVID-19 pandemic, in particular relating to the quality of a particular type of mask/filtering facepiece respirator that was purchased by HA and provided to medical, nursing and allied health services staff, as well as staff of other sectors in the clinical settings. A copy

of the Feature is annexed to this clarification letter as ***Annexure 1***.

4. As also detailed in the Feature, it was reported by MingPao that the relevant type of mask was developed, produced and supplied by Profit Royal Pharmaceutical Limited (盈宗製藥有限公司) ("**Profit Royal**"). It should be noted that Profit Royal had also supplied the masks/filtering facepiece respirators for the Study conducted by Prof. Suen. It was for this reason that Prof. Suen and our Prof. Simon Lam, one of her then study team member, were invited to comment on the incident (as detailed below) and were quoted in the Feature.

5. It has now come to our attention that after the release of the Feature, Prof. Suen and Prof. Lam have received and are still receiving frequent enquiries from different persons and stakeholders with regards to the Study and the relevant masks. After our in-depth discussion with Prof. Suen, we have taken the decision to release this Clarification to clarify and address the most enquired and relevant facts and issues relating to Prof. Suen's Study.

Background and the Study

6. In the year of 2015, well before the outbreak of the COVID-19 pandemic, Prof. Suen was introduced to Profit Royal by the Nano and Advanced Materials Institute Limited ("**NAMI**"). NAMI was established in the year of 2006 and was designated by the Innovation and Technology Commission as a research and development center for nanotechnology and advanced material. It was later let known to Prof. Suen that Profit Royal was developing a prototype of N95 respirator with nano-technology.

7. Upon further communication with Profit Royal, Prof. Suen was informed that Profit Royal's initial prototype of N95 respirator with nano-technology was available to be the subject of further testing. Prof. Suen then agreed to conduct the relevant tests with her team and two representatives of NAMI to assess various features and aspects of the prototype before and after nursing procedures, such as the mask fitness, design, usability, etc.

8. Back in the years before the Study was conducted, traditional N95 respirator was the dominant model used by healthcare professionals in clinical procedures when there was risk of exposure to airborne diseases. Due to the thickness, tightness and weight of the traditional respirators, discomfort was commonly experienced by the healthcare professionals using the same. It was Prof. Suen's intention, by testing out the newly developed prototypes of N95 respirator, to introduce such respirators

of nano-technology (technology and material known for producing lighter and thinner designs) to general healthcare professionals and improve the comfortableness and design of the respirators and ultimately the user experience.

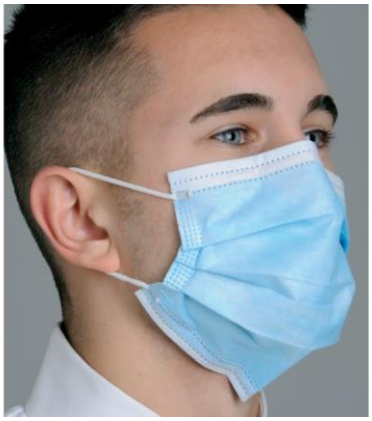
9. The Study officially began on 1 August 2015 upon receiving approval and funding from PolyU. The Study compared three types of masks: **1)** 3M 1860/1860S, **2)** 3M 1870 Plus and **3)** nanofibre mask. The former two types were two of the most commonly used types of traditional N95 masks in the hospitals in Hong Kong under HA, whilst the latter nanofibre mask was the aforementioned prototype developed and provided by Profit Royal.

10. When the Study first commenced, Prof. Suen and her team were surprised by the fact that the prototype provided by Profit Royal was a very preliminary one in all aspects and rather "premature" to be the subject of the academic study as planned. As such, Prof. Suen and her team had to invest more than a year to study and improve the design of the initial prototype provided by Profit Royal, including the material used for the nose support foam, tethering bands, etc. Prof. Suen and her team gathered comments and feedback from her research assistants and team members and relayed the same to Profit Royal for further improvement on the prototype until it was ready for the Study.

11. Most importantly and relevant to the subject of this Clarification, the prototype provided by Profit Royal for the Study had all along been of **"head-straps" design(頭帶式)**, i.e. with the two tethering bands going around the head. In fact, all subject respirators in the Study as mentioned in para.9 above were of "head-straps" design because **the objective of the Study was to study and improve the masks used in professional clinical procedures**.

A mask of "head-straps" design

12. On the other hand, the masks commonly used by the general public are of **"ear-loop"(耳掛式) design**, i.e. with two elastic cords hooking onto the ears. For the purpose of this Clarification, it should be emphasized that the two types of masks ("head-straps" and "ear-loop") are substantially different and are subject to different international standards.



A more commonly used mask of ear-loop design

13. The Study was formally completed on 31 July 2017. In a nutshell, it was found by the Study that the nanofibre mask had a better facial seal and higher usability than the two traditional N95 masks tested. It was also opined that despite the improvement made by Profit Royal based on the comments and feedback from Prof. Suen and her team at the commencement of the Study, the prototype should be further enhanced for an improved respirator fit to guarantee sufficient protection. The nanofibre mask was also found to have a significantly higher air-permeability than the other two types of traditional N95 masks, meaning it was more breathable and therefore more comfortable to wear.

    For the complete findings of the Study in detail, please refer to the article: Suen, L. K. P., Guo, Y. P., Ho, S. S. K., Au-Yeung, C. H., & Lam, S. C. (2020), Comparing mask fit and usability of traditional and nanofibre N95 filtering facepiece respirators before and after nursing procedures, *Journal of Hospital Infection*, *104*(3), 336-343. https://doi.org/10.1016/j.jhin.2019.09.014.

14. On 20 September 2019, the Article was made available online and later formally published in 2020 in the "Journal of Hospital Infection"[1], an editorially independent scientific publication of the Healthcare Infection Society. It publishes high quality research and information relating to infection prevention and control that is relevant to an international audience (impact factor of 3.926 under the Science

[1] 104 (2020) 336-343

Citation Index Expanded of 2020). The Article was also made available on the internet free of charge for reading and was expressly subject to the "Creative Commons Attribution - Non-Commercial & No Derivatives 4.0 (CC BY-NC-ND v4.0)" license ("**the License**").

15. Under the License, a user (e.g. reader) is prohibited from, amongst other things, **using the said Article or any materials therein for any commercial purposes**.

Profit Royal

16. As mentioned above, the nanofibre mask tested in the Study was the prototype provided by Profit Royal after improvement had been made as suggested by Prof. Suen and her team. Whilst Profit Royal's contribution to the Study (by providing subject masks for the Study) was a welcomed one, there was no written agreement executed between Prof. Suen (and her team) and Profit Royal for the main reason that the Study was academic in nature and was funded solely and internally by PolyU.

17. After the completion of the Study and the release of the Article, Prof. Suen and her team had no further collaboration or cooperation with Profit Royal, nor had Prof. Suen and her team made any attempt to seek from Profit Royal any official or formal acknowledgment for the team's contribution towards the development of the prototype during the Study.

18. Furthermore, as mentioned in paras.14 & 15 above, the Article is subject to a License which expressly prohibits any user from using the Article or any materials therein for any commercial purposes.

19. However, it has later come to Prof. Suen's attention that the Article had in fact been directly and fully referenced on the website of Profit Royal for apparent commercial and product promotion purposes without giving any prior notice to or obtaining any approval from Prof. Suen, the author of the Article.

20. After the release of the Feature by MingPao, all references to Prof. Suen's Study and the Article have now been removed from the website of Profit Royal. Nevertheless, ***Annexure 2*** to this Clarification is the direct screenshots of the outlook of the relevant pages on Profit Royal's website **before the deletion of the said references** and it can be observed that the Study and Article had in fact been directly referenced and quoted.

21. In particular and as will be further addressed below, a **specific section** of the Article was extracted (and translated by Profit Royal) and referenced in a section on Profit Royal's website titled "Professional Journal" to promote its several models of respirators generally named "nanofiber smart masks". This section was also removed after the release of the Feature.

22. It is now formally clarified that the references to Prof. Suen's Study and Article on Profit Royal's website were never approved by Prof. Suen, nor had she ever been notified of these references before they were put onto the website. The use of the Study and Article by Profit Royal was also highly likely to be commercial in nature for its product promotion and may have violated the License. Prof. Suen hereby expressly reserves all her rights in this regard.

Various Types of Nanofiber Masks of Profit Royal

23. There were in total **4 different models** of nanofiber masks promoted and sold by Profit Royal after the release of Prof. Suen's Article (see ***Annexure 3*** hereto):

Product Name	Design
1) NASK Nanofiber Smart Mask (PM2.5 & Sport)	ear-loop (耳掛式)
2) NASK Nanofiber Smart Mask (Bactericidal)	ear-loop (耳掛式)
3)NASK Nanofiber Smart Mask (Bactericidal Surgical Respirator)	Mixed*
4) NASK Nanofiber Smart Mask (NIOSH N95)	head-straps design (頭帶式)

**see para.25*

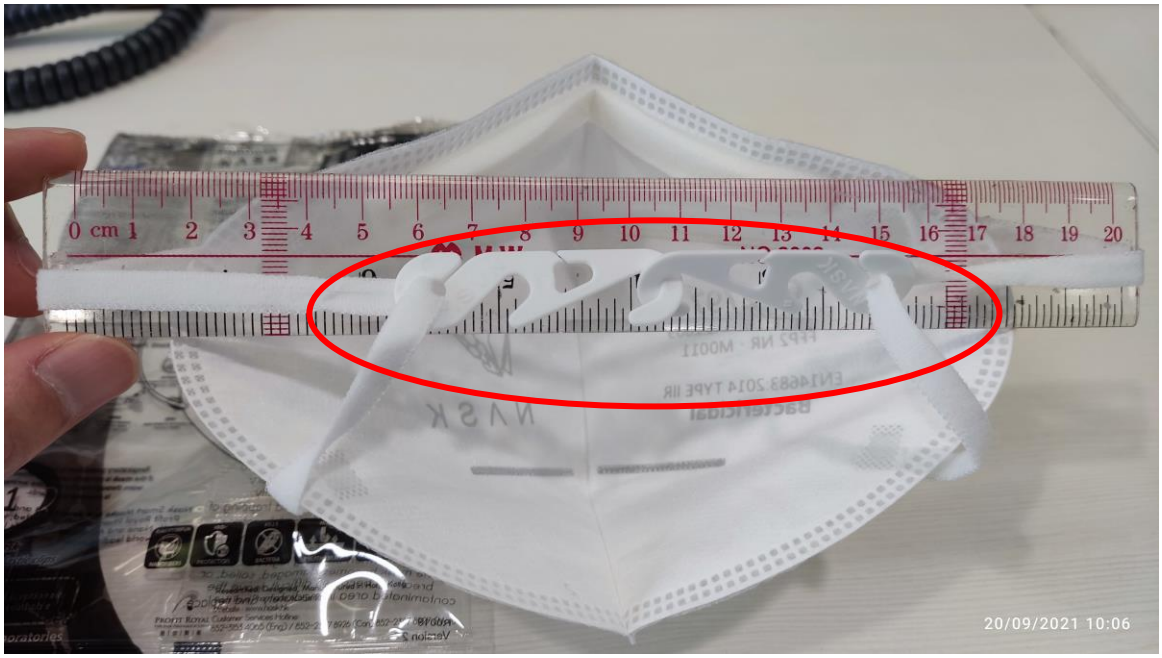
24. As shown above and in ***Annexure 3*** hereto, *(1)* and *(2)* were of "ear-loop" design and *(4)* was believed to be the developed prototype of the tested masks in Prof. Suen's Study. **Again, all tested masks in the Study were of "head-straps" design only (i.e. (4) of the above).**

25. As for *(3) NASK Nanofiber Smart Mask (Bactericidal Surgical Respirator)*, the design appeared to be an "ear-loop" one but two "S-shape clips" were added to the two elastic cords to stretch the cords and form them into a design alike a "head-

straps" one. Some wearers opted for applying only one S-shape clip to increase the tension of the tethering straps (which would also improve the passing rate of fit testing of such mask) yet compromised comfort. It should be emphasized that this design was also **not the tested subject of the Study**. This was also the model that was later sold to HA by NASK, as detailed hereinbelow.

Photos of (3) NASK Nanofiber Smart Mask (Bactericidal Surgical Respirator)

the "S-shape" clips



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the "S-shape" clip

<u>The Feature published by MingPao</u>

26. It was later publicized that amidst the outbreak of COVID-19 pandemic and the shortage of supply of masks in Hong Kong, in particular the shortage of N95 masks to healthcare personnel, the nanofibre masks developed by Profit Royal had seen a significant increase in sale.

27. For the purpose of this Clarification, it should be emphasized that Prof. Suen and her team have never been involved in any part of the commercialisation, promotion or sale of the nanofibre masks of Profit Royal.

28. Turning to the Feature published by MingPao on 28 February 2021, it was reported that HA had also purchased from Profit Royal its NASK Nanofiber Smart Mask (Bactericidal Surgical Respirator) (i.e. *Product (3)* in the table and shown in the picture above) in the year of 2020 amidst the outbreak of COVID-19 pandemic. To mitigate the then shortage of mask supply in Hong Kong, the purchased masks were soon introduced to and used by healthcare workers under HA.

29. The Feature further reported that complaints were later made by healthcare professionals about the **<u>inconsistent quality of such masks</u>**. ***Annexure 4*** hereto is a copy of the **<u>public announcement</u>** by the Association of Hong Kong Nursing Staff with regards to the said complaints. In particular, it was complained that the

"S-shape clip" for such masks had caused inconvenience to users. HA later recalled the unused batch of the said masks purchased from Profit Royal.

30. As explained above, the website of Profit Royal had made direct references to Prof. Suen's Article for promotion of its NASK nanofibre masks. As such, Prof. Suen and Prof. Lam (who also led the Study) were also enquired by MingPao about the incident and were quoted in the Feature.

31. In response to MingPao's enquiry, Prof. Suen addressed the differences between the two types of design of masks (i.e. of "head-straps" and "ear-loop" designs), background of conducting the Study, the features of the relevant masks and the relationship with Profit Royal.

32. More importantly, Prof. Suen commented and clarified that the subject mask provided by Profit Royal for the Study (i.e. the prototype as mentioned above) was of **"head-straps" design only**, whilst the ones that HA purchased from Profit Royal were not of such design (see para.25 above).

33. According to Centers for Disease Control and Prevention's recommendation on "Factors to Consider when Planning to Purchase Respirators from Another Country"[2], masks of "ear-loop" design have been recognised to have difficulties in achieving an "adequate fit", which is of utmost importance to healthcare professionals and in the Study since masks used by healthcare professionals are designed to be used in situation where there is a potential threat of air-borne diseases. **As such, the conclusion and findings of the Study are applicable strictly to its subject, i.e. masks of "head-straps" design only**.

34. As mentioned above, the Article was directly and fully referenced on the website of Profit Royal for apparent commercial and product promotion purposes without giving any prior notice to or obtaining any approval from Prof. Suen.

35. As shown in ***Annexure 5*** hereto, Profit Royal had advertised and promoted all of its different types of nanofiber masks on the catalog page of its website, yet it made no specific explanation nor drew any distinction to address the differences between the test subject mask (head-straps) and the other different types. For this reason, Prof. Suen further commented in the Feature that she reckoned the promotion of the NASK nanofibre mask by Profit Royal to be **"a little ("有少少") misleading"**.

[2] https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/international-respirator-purchase.html

36. After the release of the Feature, the original brand names of the said "NASK Nanofibre Smart Mask" have been changed. All references to Prof. Suen's Study and Article have also been removed from Profit Royal's website.

37. For the purpose of this Clarification, it is Prof. Suen's **honest and fair opinion** that the promotion of the relevant masks by Profit Royal was "a little misleading". The main reason for making this comment was that whilst her Study focused on one particular type of mask, i.e. of "head-straps" design, she felt that the Study was repeatedly referenced, quoted and used by Profit Royal as if the findings of the Study were general and applicable to other types of masks advertised on its website.

38. With regards to the unauthorized use of the Article and the potential impact on the reputation of Prof. Suen and Prof. Lam as a result of such use, all rights of Prof. Suen and Prof. Lam to take legal action and claim any loss and damages against Profit Royal are hereby expressly reserved.

Summary and Clarification

39. Given the publicity and enquiries that Prof. Suen, Prof. Lam have received after the release of the Feature published by MingPao, it has come to our decision to release this Clarification in the form of a formal written record to clarify and explain the most important and relevant issues relating to this incident.

40. The Study performed by Prof. Suen and her team in 2015 (see para.9) was intended to assess the usability of the newly developed nanofibre mask (which is known for producing lighter and thinner designs) by comparing its features with two traditional models of masks, and ultimately to introduce the use of the more comfortable model to general medical practice.

41. The Study was funded solely by PolyU and the collaboration with Profit Royal, which provided its prototype nanofibre masks as test subjects, was non-commercial in nature and there was no written agreement for the collaboration. Before the Study could proceed, Prof. Suen and her team had also made a lot of suggestions to and comments on the initial prototype provided by Profit Royal as it was reckoned to be rather premature for formal academic (medical) test. Based on their comments and feedback, Profit Royal also did later improve the prototype.

42. As the Study aimed at assessing the usability of the masks used in professional clinical procedures, **all subject masks, including the prototype provided by Profit Royal, were of "head-straps" design(頭帶式) only**.

43. On the other hand, masks of "ear-loop"(耳掛式) design are more commonly used by the general public in community settings. This is because, according to authoritative international standards, masks of "ear-loop" design tend to have difficulties in achieving an "adequate fit" for the purpose of protection against the potential threat of air-borne diseases.

44. After the completion of the Study, Prof. Suen and her team had no further collaboration with Profit Royal, nor were they involved in any part, directly or indirectly, of the later commercialisation of the prototype.

45. However, it has later come to Prof. Suen's attention that the Article was directly and fully referenced on the website of Profit Royal for apparent commercial and product promotion purposes without giving any prior notice to or obtaining any approval from Prof. Suen.

46. As the Article is subject to the License, the unauthorized use of the Article by Profit Royal for commercial purposes is a potential violation and breach of the License to say the least.

47. As Prof. Suen has later commented in the Feature published by MingPao, it is more concerning to her that the unauthorized reference to and use of the Study and Article could appear to be "misleading" to a certain extent. This is because the Study and Article, which were performed and published based on tests of **"head-straps"** masks only, were seen by her to be used by Profit Royal to advertise and promote all different types of its "NASK nanofibre masks". It should be emphasized again that these two types of masks are fundamentally different in terms of standards, level of protection, etc.

48. The Feature published by MingPao later reported that complaints were made by healthcare professionals, in particular, the Association of Hong Kong Nursing Staff, for the inferior quality of the NASK nanofibre masks. It was also reported that HA later recalled the unused masks purchased from Profit Royal. As Profit Royal had promoted its products using Prof. Suen's Article and Study, Prof. Suen and Prof. Lam were invited by MingPao to comment on the incident. Subsequently, Prof. Suen and her team members of the Study have on many occasions been enquired by different stakeholder about the incident and their Study.

49. For the reasons explained above, Prof. Suen sees Profit Royal's use of her Study and Article "a little misleading", which is an honest and fair opinion of hers. She has also addressed the differences between the two types of masks, background of

conducting the Study, the features of the relevant masks and the relationship with Profit Royal in the Feature. All references to Prof. Suen's Study and the Article have now been removed from the website of Profit Royal after the release of the Feature.

50. For the purpose of this Clarification, Prof. Suen and Prof. Lam hereby explicitly reserve all their rights in all matters relating to the potential unauthorized use of the Article and will hold Profit Royal liable for any loss and damages they may sustain as a result of the said unauthorized use of the Article, including but not limited to the potential impact on their reputation and all legal expenses incurred for this matter.]

Yours faithfully,

Tung Wah College

Annx 1_NASK_MingPao

研究採頭帶生產改耳掛 表現有差異

醫局納米口罩商引論文 學者批誤導

特稿 **醫管局去年引入本地研發的NASK納米口罩，代替一度供應緊張的N95口罩供醫護使用，惟有醫護投訴納米口罩質素參差，醫管局其後回收部分批次。NASK納米口罩網頁引用一篇由理大學者撰寫的論文，指該口罩在多方面比3M兩款口罩優勝。有份撰文的學者向本報稱，該公司向醫管局出售納米口罩爲耳掛式，論文研究的是頭帶式，批評公司仍引用其論文的數據是「誤導」。** 明報記者 **張煒明**

現為東華學院護理學院院長的孫桂萍稱不知道NASK納米口罩的網頁引用其論文。（林靄怡攝）

理大護理學院時任副教授孫桂萍、助理教授林清等2019年發表論文，稱NASK納米口罩多方面比3M兩款口罩優勝。孫向本報稱，當時研究的是頭帶式（右）口罩，NASK向醫管局出售的則為耳掛式（左），批評該公司仍引用其論文是「誤導」。（林靄怡攝）

有關論文由時任理大護理學院副教授孫桂萍及其團隊於2019年發表，比較NASK納米口罩及兩款公立醫院常用的3M1860系列及1870+系列口罩，讓104名護士學生戴上有關口罩約半小時，其間做一些醫療程序，再就口罩表現評分。結果顯示，納米口罩在透氣度、舒適度、面部壓力等8項指數，評分皆比3M口罩高，面形配合測試（fit test）合格率和細菌過濾效率亦較3M高。

撰文學者：不知道論文被上載

現爲**東華學院護理學院院長的孫桂萍**接受本報查詢稱，當時用於研究的NASK納米口罩爲頭帶式，並非耳掛式，「同佢喺家賣畀HA（醫管局）個model係幾唔同」，她並不知道該公司將其論文放於網站，亦無通知她，「我就覺得有少少misleading（誤導），我份paper（論文）係用過頭（頭帶式），佢用另一方式固定」。她說「過頭同掛耳係有分別，國際上有標準」。

美國疾病管制與預防中心網頁指出，購買耳帶式呼吸器時要小心，因耳帶式呼吸器難達到適當面形密合度（adequate fit），而美國國家職業安全衛生研究所（NIOSH）認證的口罩一般並非耳帶式。

孫桂萍說，當初並不認識研發NASK納米口罩的盈宗製藥，數年前由納米及先進材料研發院（NAMI）介紹認識對方，得悉對方想以納米技術研發口罩，遂以其學院資源及內部撥款，看看如何改善其產品的原型，「我哋用咗成年幫佢改善鼻托、頭帶，畀咗一啲意見」、「同佢去鴨寮街四圍搵，用邊啲物料最好」。她說研究期間雙方無簽協議，亦無參與其商品化的工作，論文刊出後欲邀請對方合作其他研究，對方不太積極回應。後來她從NAMI得知該口罩在日內瓦贏得發明獎項，對方亦無答謝其團隊。

廠商：受邀提供產品作研究 無合作關係

盈宗製藥回應稱，2015年收到孫桂萍及其團隊邀請，希望該公司提供口罩作研究，强調該公司是受邀，未與對方建立任何合作關係。該公司其後將研究結果放於網上供市民查閱，從未收過孫桂萍或其團隊要求將論文下架。本報翻查NASK網頁，在產品介紹下仍有頭帶式及耳掛式兩款口罩。

另外，本報發現該納米口罩兩個批次的耳帶長度約有0.5厘米分別，有醫護人員指醫管局未有再安排前線醫護做fit test。有份撰寫論文的**理大護理學院助理教授林清**稱，根據其研究，如口罩的耳帶或頭帶力度有變，其面形配合度亦會改變，醫護應重新做fit test。負責認證該口罩的**英國標準協會（BSI）**回應稱，如耳帶長度有變，需再提交口罩予該會認證。盈宗製藥未正面回應有否再向BSI提交口罩，只稱獲第三方包括BSI定期到生產廠房評審，確保口罩符合國際標準。**醫管局**稱已向製造商反映員工對該口罩耳掛繩長度的關注，如員工懷疑口罩不合適，可重新做fit test。

本報早前報道，供應醫管局的納米口罩並無跟隨歐盟要求，將相關歐盟標準及級別等規格印在每一個口罩表面。BSI早前稱會調查事件。BSI近日回應本報稱已完成調查，因保密原因未能交代結果。**香港海關**稱暫未發現有違反《商品説明條例》情況。

理大研可調頭帶N95 已供醫局測試

理大護理學院助理教授林清及其團隊近日與本地生產商合作，研發出一款可調校頭帶長度的N95口罩，並已註册專利，有望大量生產供醫護使用。他說已向醫管局提供口罩樣本作測試，商討合作的可能性。

2003年SARS爆發時爲前線醫護的林清說，深深體會到保護裝備的重要，並經常免費爲不同有潛質的生產商改良口罩設計，自言「國難當前，匹夫有責」。他說早前和一間本地口罩生產商合作，希望研發一款適合不同臉形的口罩，研究時冀以環保爲原則，不希望外加其他如耳帶扣等物料。

已申專利 稱面形配合度八成合格

他以加上刻度的合成橡膠製造該口罩的頭帶，以特別方法釘裝，未戴上時可調校頭帶長度，並可記下刻度，方便下次再戴時調整。戴口罩時，使用者需反起頭帶，頭帶便不會再「走位」。早前研究數據顯示，該口罩面形配合度的合格率達八成。被問及會否採用該款口罩，**醫管局**回應稱，外科呼吸器供應持續緊張，會繼續研究其他替代產品。

林清2001年畢業後在公立醫院當護士，SARS爆發時在威爾斯親王醫院工作，在首先爆疫的8A病房停止運作後，協助重開一個分流病房，其間自己亦接觸到一名SARS病人，其後他身體產生抗體，幸没發病。他說SARS爆發前，醫護一般不戴口罩，認爲是尊重病人的表現，SARS後大家更着重保護裝備。

理大護理學院助理教授林清及其團隊近日與本地生產商合作，研發出一款可調校頭帶長度的N95口罩，並已註册專利。（林靄怡攝）

林清2006年因患眼疾，被迫從前線退下，轉爲執教鞭，先在公開大學任教12年，其後轉到理大。他在公大時受其上司、立法會前議員李國麟所託，爲一些準備到醫院實習的學生安排口罩fit test，開展其研究口罩工作，「人生去到某一步，睇番轉頭先知嗰一點係有用」。

Journal of Hospital Infection – Comparing 3M N95 and NASK Nanofiber N95 before and after nursing procedures

Please see the enclosed paper of a research study "Comparing 3M N95 and our N95 before and after nursing procedures (Suen LKP et al., Journal of Hospital Infection, http://doi.org/10.1016/j.jhin.2019.09.014)" for your reference. The paper can be summarized as below:

Conclusions

In the study, mask fitness test and usability satisfaction survey were conducted in order to evaluate the applicability of the nanofiber smart mask, benchmarking with the "best-fitted respirator" including "3M's 1860 series" and "3M's 1870 plus".

104 subjects were involved in the study.

All masks used in the study were N95-certified by NIOSH.

2 major conclusions can be drawn from the study:

1. The overall fit factor of the nanofiber smart mask is higher than that of the "best-fitted respirator", no matter whether the fit factors are determined before or after nursing procedures.
2. The usability (i.e. user satisfaction) of the nanofiber smart mask is significantly higher than that of the "best-fitted respirator" in all investigated aspects including "heat", "breathability", "tightness", "ease in talking", "mist over glasses", "itchiness", "difficulty of maintaining the mask in place" and comfort on ear lobe".

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Journal of Hospital Infection 104 (2020) 336–343

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Journal of Hospital Infection – Comparing 3M N95 and our N95 before and after nursing procedures

請參閱研究報告的所附論文"Comparing 3M N95 and our N95 before and after nursing procedures "（Suen LKP等人，Journal of Hospital Infection，http：//doi.org/10.1016/j.jhin.2019.09.014）。 本文總結如下：

結論

本研究旨在透過口罩密合性測試及用家滿意度調查以評估納米纖維智能口罩之適用性，並以" 3M的1860系列"和" 3M的1870 + " 口罩作對照，對照的選擇取決於口罩在測試對象上之密合性，以密合性較佳之口罩作對照。

本研究包括了104名測試對象。

研究中使用的所有口罩均獲得NIOSH N95認證。

主要結論結果如下：

1. 無論測試對象於進行護理工作前或後作密合性測試，結果均顯示納米纖維智能口罩之密合性優於對照之口罩。
2. 用家滿意度調查顯示納米纖維智能口罩之用家滿意度在所有本研究包括之範疇均優於對照之口罩，研究範疇包括"悶熱度"，"透氣度"，"鬆緊度"，"說話容易度"，"眼鏡起霧情況"，"痕癢度"，"調整口罩位置容易度"及"耳垂舒適度"。


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Healthcare Infection Society

Comparing mask fit and usability of traditional and nanofibre N95 filtering facepiece respirators before

Annx 3_masks type (english)

NASK Nanofiber Smart Mask (PM2.5 & Sport)

World’ s 1st Nanofiber PM2.5 mask – A Grade (Highest Protection)

Special-Use Edition

Technology Merits

- 2017 Geneva International Invention "A + Gold Award"
- The world's first nanofiber PM2.5 mask
- Integrated P95 (Oily) / N95 (Non-oily) Filter materials
- Effectively block oily and non-oily pollutants in the air, including Most Penetrating Particles Size(MPPS) and PM2.5 particulate contaminants

Competitive Advantage

- Ultra-thin, Ultra-breathable, Ultra-lightweight, providing wearers with high protection and comfortability
- Athletes blood oxygen level remains normal after wearing mask for strenuous exercise
- Meet international standards for filtering P95 (oil resistance) and N95 (non-oil resistance) pollutants
- Effectively filter invisible pollutants, viruses, car exhaust, second-hand smoke, formaldehyde, dust mites, haze, volatile chemicals in the air

Application

- Special-use masks for workers in severe air pollution, construction sites and sweltering environments
- Special-use masks for athletes exercising outdoor to combat polluted environment
- Effectively blocks viruses, bacteria, and air pollutants, can be used in the medical and health care industry

Con’ t

NASK Nanofiber Smart Mask (NIOSH N95)

Feather-light & Breathable NIOSH Certified Respirator

Professional Edition(NIOSH)

Technology Recognition

- The world ’s first NIOSH N95 certified nanofiber mask (Approval No. TC-84A-7761)
- Effectively improve inadequate protection of traditional surgical mask and poor breathability of current N95 respirators
- NASK's patented nanofiber technology has better performance in terms of filtration efficiency, air permeability and protection compared to well-known brands in the world (see Journal of Hospital Infection https://www.sciencedirect.com/science/article/pii/S0195670119304025)
- Light weight nanofiber membrane to achieve high filtration efficiency with low breathability resistance
- Bacteria Killing (Nelsen Labs, US: Kills over 99% of Bacteria within 5 minutes)

Competitive Advantage

- The high specific surface area of nanofibers increases the dust loading capacity, and the filtration efficiency of NaCl particles >95% (Nelsen Labs, US: > 99% Filter Efficiency)
- Highly breathable, inhalation and exhalation resistances are less than 13 and 9 (mmH2O) vs NIOSH requirements: inhalation and exhalation resistances are 35mm and 25mm H2O respectively
- Suitable for whole day use without intermittent
- Filter pollutants with different particle sizes in the air, including Most Penetrating Particle Size (MPPS) - 0.26-0.3 micron particles

Con’ t

NASK Nanofiber Smart Mask – (Bactericidal Surgical Respirator)

World' s 1st CE Certified Nanofiber Bacteria Killing Surgical PPE

Professional Edition(CE)

Technology Recognition

- World' s 1st CE Certified Nanofiber Bactericidal Surgical Personal Protective Device (PPE) (FFP2+IIR)
- Bacteria Killing* (Nelsen Labs, US : Kills over 99% of Bacteria within 5 minutes)
  * (Tests include Staphylococcus aureus, Pseudomonas aeruginosa, Streptococcus pneumoniae and Klebsiella pneumoniae)

Competitive Advantage

- High protection against leakage from side seals (BSI, UK : FFP3 level)
- High protection in the hospital environment (Nelsen Labs, US : Type IIR level)
- Effectively block oily and non-oily pollutant particles (BSI : NaCl Exposure Test > 99% - FFP3 level, Paraffin Oil Exposure Test > 95% - FFP2 level)
- Low Inhalation resistance (BSI, UK : FFP3 level)
- Protects against oil mist, metal shavings, toxic solids, liquid or radioactive particles, and high-contamination Environment
- Over 8 hours of continuous use

Application

- Professionals including doctors working in CDC, dentists, medical staff and laboratory personnel
- Provide workers with PPE in extremely harsh indoor / outdoor areas to filter out toxic chemicals and particles in the air (e.g. carcinogenic particles emitted during laser surgery operations)
- Suitable for all kinds of metal work, high fine dust and highly polluted environment

Con' t

NASK Nanofiber Smart Mask (Bactericidal)

The 1st N99 Nanofiber Bacteria Killing Mask - Comfort and Strong Protection

Premier Edition

Technology Merits

■ **Bactericidal Function**

- The patented technology exhibiting bactericidal function to minimize cross-contamination
- The world' s Unique Nanofiber Bactericidal Mask with N99 filtration efficiency
- kill major groups of bacteria (Pseudomonas aeruginosa, Staphylococcus aureus, Streptococcus pneumoniae and Klebsiella pneumoniae) *

  * Nelsen Labs, US, kills over 99% of Bacteria within 5 minutes

■ **Respiratory Comfort**

- The porous structure of nanofibers allows NASK to achieve high filtration efficiency with low air resistance. It is also light to wear.
- Phenomenon of mist over glasses is not observed
- High breathability and can be worn during sleep with the blood oxygen level remains unchanged

■ **Filtration by Multiple Mechanism**

- Trap airborne contaminants of various sizes including the Most Penetrating Particle Size (MPPS)
- The specific surface area ratio of ordinary materials is increased by more than 10,000 times and leads to a higher loading capacity
- Blocks viruses such as SARS, chicken pox, various types of influenza, measles and even Ebola

Con' t

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香港護士協會 ASSOCIATION OF HONG KONG NURSING STAFF
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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

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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**

我們已去信醫管局要求局方正視並解決有關的問題，確保同業在工作時獲得合適的防護裝備，為同業提供足夠的保障。

如有任何問題，請與我們聯絡。

香港護士協會
副主席 楊綺雯
二零二一年一月二日

union@nurse.org.hk
2314 6962
香港護士協會(AHKNS)

Annx 5_NASK Products catalog

NASK

NASK Nanofiber Smart Mask – (Bactericidal Surgical Respirator)

World' s 1st CE Certified Nanofiber Bacteria Killing Surgical PPE

Professional Edition(CE)

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Con' t

NASK Nanofiber Smart Mask – (Bactericidal Surgical Respirator)

World' s 1st CE Certified Nanofiber Bacteria Killing Surgical PPE

Professional Edition(CE)

Certificate

- CE PPE : Category III - BSI (CE2797) Full Certification (EU Standard EN149:2001 + A1:2009)
- Bacteria Killing (Nelsen Labs , US : Kills over 99% of Bacteria within 5 minutes)
- US / EU Medical Device Grade (US ASTM F2100-11 Class 1 Level 2 Barrier / EU Standard EN14683:2014 Type IIR level)

Design

- 4D Design
- Ear-loop with 2 S-shape plastic clips; Easy to wear
- One-for-all Size

Packing

- Single piece per pack, hygiene and safe to use
- Adult – 5 pcs or 50 pcs per box with 100pcs of plastic clips;