

Assessment of Two Personal Breathing Recording Devices in a Simulated Healthcare Environment

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ABSTRACT

Background: In the field of respiratory protection for healthcare workers (HCWs), few data are available on respiratory airflow rate when HCWs are performing their work activities. The objective of this study was to assess the performance of two wearable breathing recording devices in a simulated healthcare environment.

Methods: Breathing recording devices from two different manufactures “A” and “B” were assessed using 15 subjects while performing a series of simulated healthcare work activities (patient assessment; vitals; IV treatment; changing linen; carrying weight while walking; normal breathing while standing). The minute volume (MV, L/min), mean inhalation flow (MIF, L/min), peak inhalation flow (PIF, L/min), breathing frequency (f, breaths/min), and tidal volume (TV, L/min) measured by each device were analyzed. Bland-Altman method was applied to explore the variability of devices A and B. Duncan’s multiple range test was used to investigate the differences among activity-specific inspiratory flow rates.

Results: The average MV, MIF and PIF reported by device A were 23, 54, and 82 L/min with 95% upper confidence intervals (CIs) of 25, 60 and 92 L/min; the mean differences of MV, MIF and PIF presented by the two units of device A were 0.9, 1.3, and 2.8 L/min, respectively. The average values and mean differences of MV, MIF and PIF found with device B were significantly higher than device A ($P < 0.05$), showing a high variability. During non-speech activities, the PIF/MV and MIF/MV ratios were >3.14 and >2 , while with speech, the ratios increased to >6 and >3 . The f during speech (15 breaths/min) was significantly lower than non-speech activities (20-25 breaths/min). Among different simulated work activities, the PIF of “patient assessment” was the highest.

Conclusions: This study demonstrated a novel approach to characterize respiratory flow for healthcare workers using an innovative wearable flow recording device. Data from this investigation could be useful in the development of future respirator test standards.

Keywords: Healthcare worker, breathing, respiratory flow, powered air-purifying respirator, minute volume, peak inhalation flow

INTRODUCTION

Healthcare workers (HCWs) are at risk for exposure to various infectious respiratory viruses (such as the highly prevalent and seasonal respiratory syncytial virus) and bacterial pathogens (OSHA 2007; Liverman and Larson 2011; IOM 2015). Currently, there are 18 million U.S. HCWs relying on personal protective equipment (e.g., respirators, gloves, gowns, face shields, etc.) when exposed to a range of known and unknown occupational infectious agents (CDC 2012). Traditionally, surgical masks and N95 filtering-facepiece respirators (FFRs) are widely used to reduce exposure to airborne hazards in healthcare settings, even though various studies have demonstrated that surgical masks offer minimal protection, and N95 FFRs are not comfortable to use due to the increased air resistance of the filter (Davidson et al. 2013; He et al. 2013, 2014a b; Rengasamy et al. 2014). Following the 2009 severe acute respiratory syndrome (SARS), 2009 H1N1 influenza, and Ebola outbreaks, significant attention has been directed towards using powered air-purifying respirators (PAPR) for HCWs (IOM 2015).

According to the U.S. Occupational Safety and Health Administration (OSHA), a PAPR is “an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering” (OSHA 2006). There are two types of PAPR: 1) tight-fitting (full facepiece or half-mask facepiece) designed to seal to the face or neck, and 2) loose-fitting (hood, helmet, or loose-fitting facepiece) designed to cover, but not seal completely to, the face or neck. The U.S. National Institute for Occupational Safety and Health (NIOSH) certifies respiratory protection devices including PAPRs (OSHA 1998). One of the NIOSH certification criteria is the minimum air flow rate: tight-fitting PAPRs must provide a constant flow of at least 115 L/min, and for loose-fitting PAPRs it is 170 L/min. Compared to N95 FFRs, PAPRs feature several advantages to the wearers. PAPRs offer higher assigned protection factors (APFs) ranging from 25 to 1000, whereas the APF for N95 FFRs is only 10 (OSHA 2006). In addition, loose-fitting PAPRs do not require annual fit testing, and they can be used by HCWs who cannot achieve a good faceseal due to facial hair or other factors (Roberge 2008). Another significant benefit offered by PAPRs is the airflow supplied by the blower can overcome the pressure resistance of the filter as well as reduce heat build-up inside the worker’s breathing zone, adding to the overall comfort of wearing PAPRs.

The performance of both FFRs and PAPRs are significantly affected by users’ inspiratory flow rate (He et al. 2014a b; Mackey et al. 2005). The influence of testing flow on N95 FFRs have been studied extensively (Coffey et al. 2004; Grinshpun et al. 2009; Rengasamy et al. 2012; Zhuang et al. 2013). However, PAPRs have received much less research attention (Cohen et al. 2001; Roberge et al. 2008). PAPRs were originally developed in the 1960’s to protect industrial workers from respiratory and dermal hazards (IOM 2015). A silica dust loading test incorporating the complete PAPR system is part of the NIOSH testing requirements. This test simulates a work condition found in industrial settings, primarily in mining. Industrial settings such as mining are often associated with moderate to high exertion job activities. This means that PAPRs used in those conditions must supply sufficient air to satisfy the high breathing demands for the workers. The workplace environments experienced by HCWs differ significantly from industrial conditions, especially when it pertains to physical exertion for routine work activities (ISO/TS 16976-1:2015). One significant challenge to using PAPRs is the cost. The average price of a PAPR currently sold on the U.S. market is about \$1,000 (IOM 2015). By reducing the capacity of individual elements, the cost of a newly developed “low-flow” PAPR may be reduced, making them

more affordable. One complaint from HCWs when using traditional PAPRs is the wind noise produced by the high air flow, which can interfere with communication and affects workers' ability to perform certain tasks effectively (Khoo et al. 2005). This problem may be lessened with the new "low-flow" PAPR class as well.

Currently, few published data are available regarding the breathing flow needed by HCWs when performing their work activities. Given that a loose-fitting PAPR facepiece does not form a tight fit to its wearer, its air flow supply must be adequate to prevent airborne contaminants from entering the facepiece. It would be very helpful if inspiratory flow rates of HCWs are characterized for different types of work, which could help determine the minimum operational flow that is required for PAPRs when used by HCWs. The objective of this research was to assess airflow rates of two different types of wearable/portable breathing recording devices using 15 subjects in a simulated healthcare environment. The purpose was to optimize the sampling system and compare the performance of the two types of devices. The model with lower variability will be selected in future field studies to characterize HCW's respiratory flows.

METHODS

Instrumentation

Four breathing recording devices from two different manufacturers "A" and "B" (two units of devices for each type: A1, A2, B1 and B2) were employed to evaluate the variability of each model. As shown in Fig.1, both devices A and B employ a pressure data logger module which can be hung on a belt or put in a pocket, thus allowing continuous respiratory flow monitoring for different types of occupational work. Each device contains a differential pressure sensing system that uses a mask-mounted sensor to measure the pressure drop inside the mask (see Fig.1). Then the pressure data is converted to breathing flow data via a calibration curve. Detailed specifications for devices A and B are listed in Table I.

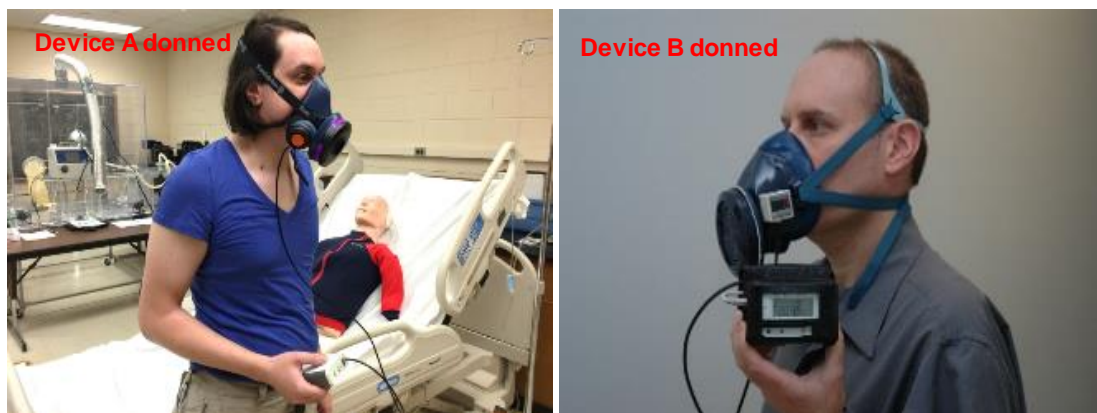


Fig. 1. Breathing recording devices A and B.

Participants

A group of 15 human subjects (eight male and seven female) was recruited for this laboratory based study. Institutional Review Board (IRB) approval from West Virginia University (WVU) was obtained

prior to subject recruitment. Before participating in the test, subjects were given the OSHA Respirator Medical Evaluation Questionnaire (OSHA 1998). Only those who were medically cleared based on the questionnaire were allowed to continue this study. Subjects' age, weight, and height were 27.3 ± 3.9 years, 69.8 ± 12.9 kg, and 171.7 ± 10.5 cm (means \pm standard deviation), respectively.

Table I. Specifications of Breathing Recording Devices A and B

Categories	Device A	Device B
Maximum measurement (L/min)	400-500	220
Sampling interval (sec)	0.02	0.1
Sampling duration	8hr	13min
Data storage capacity	1.44×10^6	8000
Coupled respirator size	S/M, M/L, L/XL	M/L
Weight (g)	<450	<540

Experimental Set-up

A manikin lying on a hospital bed was set in the laboratory to simulate the hospital environment. Infusion support and apparatus were set beside the bed to allow the human subjects to simulate intravenous (IV) treatment. Likewise, a sphygmomanometer and an echometer were employed to simulate the activities of measuring blood pressure and heart rate. In addition, the temperature, humidity and noise were kept as 23~27°C, 40-60%, 40-60dB, respectively, which were consistent with the real hospital workplace environment. The simulated healthcare environment is depicted in Fig. 2. Individual subjects each wore all four devices and performed six activities to simulate routine tasks commonly seen in healthcare settings (see Table II). It should be noted that "Patient Assessment—asking questions" was the only activity that involved speaking, while all other five were "non-speech" activities. Each activity lasted 1-min and was repeated once. There was 1-min break between each activity run. A randomized block design was applied in this study. For each subject, a breathing recording device was randomly chosen, and the 6 activities were fully randomized for each device to minimize the effect of experimental error. The experimental conditions are summarized in Table II.

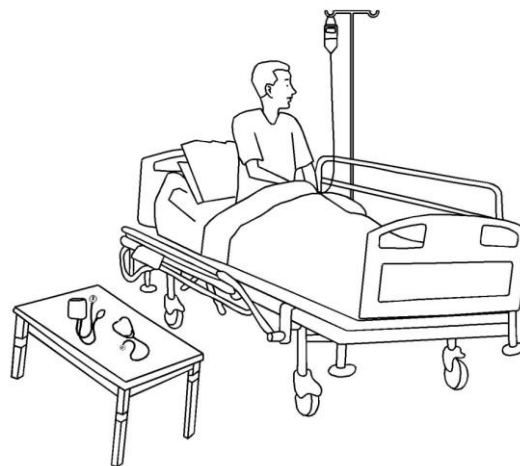


Fig. 2. Simulated healthcare environment.

Table II. Summary of Experimental Conditions

Variable	Levels
Device	2 units of device A (A1 and A2), 2 units of device B (B1 and B2)
Subject	15 human subjects
Activity	1. Patient Assessment (PA)—asking questions 2. Vitals (V)—measuring blood pressure and heart rate 3. IV Treatment (IV)—administering IV care using a manikin 4. Changing linen (CL) 5. Carrying a 5 lb weight while walking (CW) 6. Normal breathing while standing (NB)
Replicates	2
Total runs	4×15×6×2=720

Breathing Parameters Measured

The minute volume (MV, L/min), mean inhalation flow (MIF, L/min), peak inhalation flow (PIF, L/min), breathing frequency (f, breaths/min), and tidal volume (TV, L/ breath) were measured by the four devices; additionally, the PIF/MV and MIF/MV ratios were calculated. The definition of each parameter is listed in Table III. MV was the output of the device; MIF was calculated as MV divided by inhalation time; PIF was obtained as the average value of a series of breath cycles; f was counted as the number of breath cycles per minute; TV was calculated as MV divided by f.

Table III. Definitions of Inhalation Parameters

Parameter	Description
Minute volume (MV, L/min)	Air volume inhaled in one minute
Mean inhalation flow (MIF, L/min)	Mean flow rate during inhalation phase
Peak inhalation flow (PIF, L/min)	Average of peak inhalation flow rates of a series of breaths
Breathing frequency (f, breaths/min)	Number of breath cycles in one minute
Tidal volume (TV, L/breath)	Air volume inspired during each breath

Data Analysis

The variability of each model of devices A and B, as well as the agreement between them was investigated by Bland-Altman plots, a graphical agreement evaluation method, through which the distribution of differences and their change with average measurement can be observed directly. By adding mean difference (bias) and 95% limit of agreement (LoA) into the plot, the agreement between two devices can be evaluated (Bland and Altman 2003, 2007). Mean differences and 95% LoAs of MV, MIF and PIF were calculated and presented in the Bland-Altman plots. Duncan's multiple range test was applied to investigate the differences among activity-specific MV, MIF and PIF. All data analyses were performed using SAS version 9.3 (SAS Institute Inc., Cary, NC, USA). A P-value < 0.05 was considered significant.

RESULTS AND DISCUSSION

Performance Evaluation of Device A

The measurements of breathing responses to different activities by devices A1 and A2 are shown in Table IV. Regardless of different activities, the overall average MV obtained by device A (A1 and A2) was 23 L/min with 95% confidence interval (CI) of 20-25L/min. Since MVs for a medium sized people (body surface area=1.84m²) to perform light, moderate and heavy workloads are 15, 30, and 85 L/min, respectively (ISO/TS 16976-1:2015), the data measured by device A reasonably reflected the MV needed by the subjects (body surface area=1.81 ± 0.22 m²) when performing the six light-moderate activities in the study. The average MIF was 54 L/min with 95% CI of 48-60L/min, significantly lower than the NIOSH approval test flow (85 L/min) for N95 FFRs. The average PIF was reported as 82 L/min with the upper 95% CI of 92 L/min, indicating that future development of NIOSH PAPR standards may consider lowering the 170 L/min minimum operational airflow for loose fitting PAPRs. Since this is a lab-based simulation study, the above findings need to be further verified in the real healthcare settings.

Table IV. Measurements of Breathing Responses to Activities by Devices A1 and A2

Parameter	Device	PA	V	IV	CL	CW	NB
MV (L/min)	A1	16.5±3.2	22.4±4.0	23.7±2.9	27.9±4.2	26.8±3.1	20.7±3.2
	A2	16.4±5.2	20.6±4.7	22.5±4.3	26.9±4.6	26.3±4.6	19.3±4.0
MIF (L/min)	A1	51.4±12.3	53.1±8.5	55.3±7.8	62.3±10.5	59.4±8.0	46.2±7.1
	A2	52.4±10.1	50.0±12.5	53.6±11.8	61.3±11.7	58.1±10.4	44.1±9.6
PIF (L/min)	A1	96.8±17.2	76.8±18.7	78.8±13.4	92.7±23.8	86.6±18.2	69.0±12.7
	A2	95.1±19.5	72.2±18.9	76.7±15.9	89.3±18.8	87.8±24.5	63.2±13.2
*95% UCI of PIF (L/min)	A1	105.5	86.2	85.6	104.8	95.8	75.4
	A2	100.1	77.0	80.8	94.2	94.1	66.6
PIF/MV	A1	5.97±0.93	3.44±0.65	3.34±0.64	3.33±0.78	3.22±0.54	3.36±0.60
	A2	6.07±1.51	3.49±0.44	3.44±0.53	3.33±0.39	3.34±0.66	3.30±0.37
MIF/MV	A1	3.17±0.65	2.38±0.16	2.33±0.20	2.23±0.17	2.21±0.12	2.25±0.21
	A2	3.37±0.84	2.40±0.24	2.39±0.32	2.28±0.14	2.22±0.16	2.30±0.35
f (breaths/min)	A1	17±2	23±3	23±4	25±4	25±4	20±3
	A2	16±2	23±3	22±3	26±5	25±4	20±3
TV (L/breath)	A1	1.00±0.18	0.99±0.19	1.07±0.15	1.13±0.23	1.11±0.17	1.04±0.18
	A2	1.06±0.37	0.94±0.24	1.03±0.22	1.06±0.24	1.09±0.25	0.99±0.26

Note: *Indicates the 95% upper confidence interval (UCI) of PIF.

The MV, MIF, PIF, f, and TV during different activities measured by devices A1 and A2 were not significantly different ($P>0.05$), suggesting that the breathing recording device A has a small variability. Duncan's multiple range test was also applied to investigate the differences among different activities reported by A1 and A2. The groupings of MV, MIF, and PIF reported by A1 and A2 were almost in the same order (see Table V), which further confirmed the low variance between A1 and A2. Among the six activities, the MV during patient assessment (PA)—asking questions was the lowest (16 L/min), while the highest MV of 26-28 L/min was recorded during changing linen (CL) and carrying a 5lb. weight while

walking (CW). MV reported for all other activities were approximately 20 L/min. The lowest MIF of 45 L/min was found for subjects performing normal breathing while standing (NB) instead of PA. MIF of CL was the highest, slightly over 60L/min. As expected, the PIF of PA ranked the highest, since subjects kept talking in this process, while speech happened during the exhalation phase, correspondingly the inhalation time would be reduced, thus the subject had to increase the PIF to get enough air inhaled.

Table V. Duncan's Groupings of MV, MIF, and PIF for Devices A1 and A2

Activity	MV		MIF		PIF	
	A1	A2	A1	A2	A1	A2
PA	E	E	C	C	A	A
V	C	C	BC	C	D	C
IV	B	B	B	C	D	C
CL	A	A	A	A	B	B
CW	A	A	A	B	C	B
NB	D	D	D	D	E	D

Note: Inspiratory flows during activities with the same letter are not significantly different ($P>0.05$).

Interestingly, during non-speech activities, the PIF/MV ratios were generally greater than 3.14. It is well known that human breathing pattern can be represented by a sinusoidal waveform, and the PIF/MV ratio equals π or approximately 3.14 (Cooper 1960). This study, however, indicates that actual human breathing flow patterns may be different from the sinus cycle. It has been concluded that PIF rates were 2.5 to 3.7 times as high as the MV (Silverman et al. 1945; Lafortuna et al. 1984; Kaufman and Hastings 2005). The PIF/MV ratios obtained in this study were between 3.3 and 3.5, which was consistent with those studies. Under speech conditions, the PIF/MV reached as high as 6, similar ratios (PIF/MV=6) have been reported by Holmér et al. (2007). As discussed above, during the PA process, the inhalation time was reduced. Thus PIF/MV was increased (i.e., two times) to ensure adequate air supply to the human body. Similarly, for the MIF/MV ratios during no speech activities, the MIF/MV ratios were slightly higher than 2.0, which means that during those light to moderate activities, the subject spent less than half of the time inhaling. The breathing frequency (f) during speech was 16 breaths/min, which was significantly lower than any other non-speech activities (20-26 breaths/min). This was probably caused by the relatively longer time spent for speaking, resulting in extended exhalation time and longer breath cycle time— the longer the cycle time, the lower the breathing frequency would be. The values of TV were relatively unchanged among different activities (1-1.1L/breath). Combined with the variation of f among different activities (see Table IV), it was concluded that the increase of MV was mainly attributed to the increase of f. This finding suggests that with the increased workload from light to moderate, human breath is faster rather than deeper.

To further analyze the variability between devices A1 and A2, the mean differences and 95% LoAs of MV, MIF and PIF for devices A1 and A2 were obtained and presented in the Bland-Altman plots, as shown in the Fig. 3. The mean differences of MV, MIF and PIF between devices A1 and A2 were 0.9, 1.3, and 2.8 L/min, which were all close to zero, demonstrating the low variability of device A.

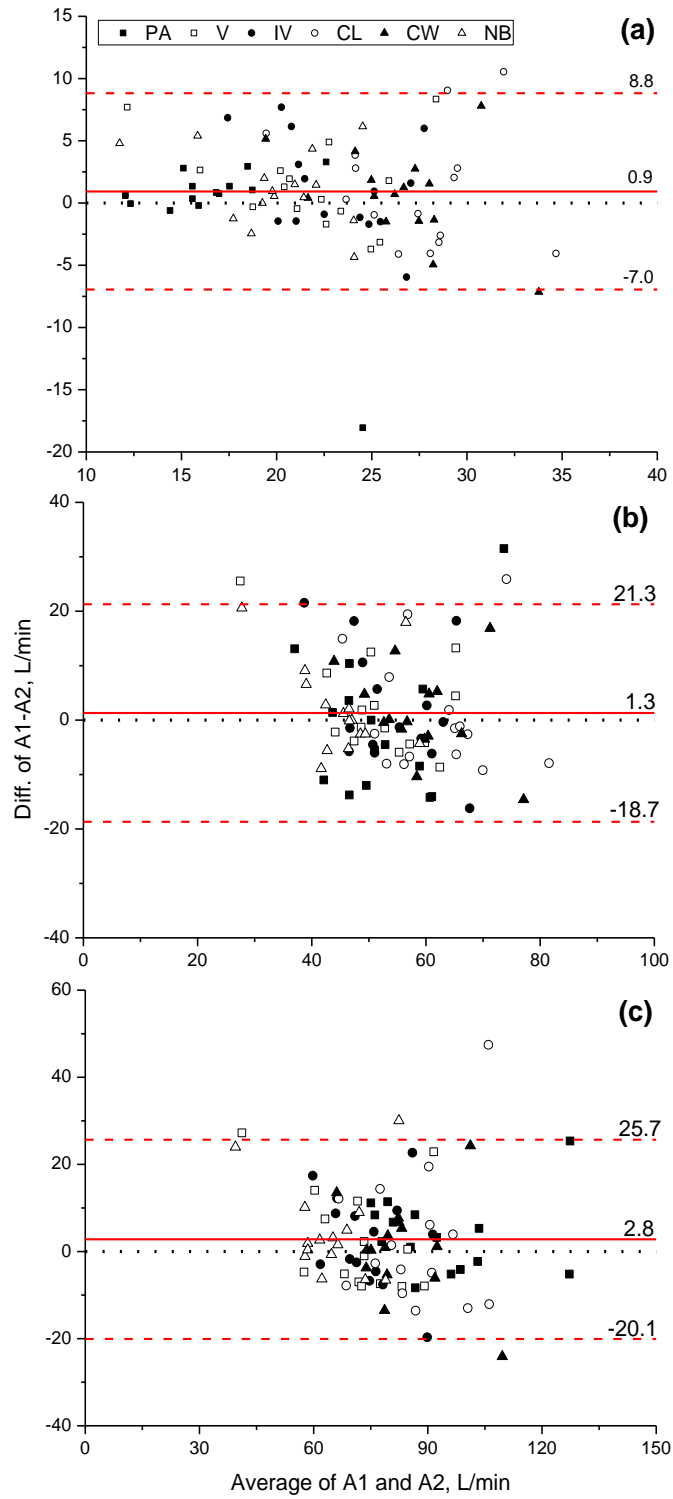


Fig. 3 Bland-Altman plots of MV (a), MIF (b) and PIF (c) for devices A1 and A2. The solid line indicates mean difference; the dashed lines indicate 95% LoAs; the dotted line represents mean difference of 0.

Performance Evaluation of Device B

The breathing responses to different activities measured by devices B1 and B2 are shown in Table VI. Among different activities, the overall average MV, MIF and PIF reported by devices B1 and B2 were 29, 75, 123 L/min with 95% CIs of 19-38, 47-103, and 72-174 L/min, respectively, which were significantly higher than the corresponding values presented by device A (A1 and A2). Both devices A and B confirmed that the six simulated activities (see Table II) could be classified as light-moderate workload activities, and the 170 L/min minimum operational airflow was adequate for loose fitting PAPRs worn by HCWs.

Table VI. Measurement of Breathing Responses to Activities by Devices B1 and B2

Parameter	Device	PA	V	IV	CL	CW	NB
MV (L/min)	B1	38.6±26.7	27.6±18.9	28.9±17.2	39.0±24.6	38.9±21.3	23.4±13.7
	B2	23.0±14.7	20.7±12.0	23.3±12.0	32.6±17.7	32.5±18.7	18.7±11.2
MIF (L/min)	B1	119.0±99.6	64.7±41.9	69.5±46.6	89.6±60.6	86.8±51.0	56.0±35.5
	B2	97.9±71.8	54.3±32.1	57.8±29.3	81.1±45.7	77.6±46.0	48.7±29.5
PIF (L/min)	B1	221.5±202.4	110.0±79.5	106.4±67.8	143.4±97.4	141.0±81.8	87.6±55.7
	B2	177.7±146.7	84.9±51.7	89.5±49.7	123.5±68.5	117.4±66.9	73.2±48.1
95% UCI of PIF (L/min)	B1	323.9	150.2	140.7	192.7	182.4	115.8
	B2*	215.6	98.3	102.3	141.2	134.7	85.6
PIF/MV	B1	5.71±1.82	4.44±1.61	3.57±0.41	3.56±0.45	3.63±0.44	4.00±1.42
	B2	7.91±2.47	4.42±1.47	3.91±0.75	3.96±0.86	3.78±0.80	4.10±1.08
MIF/MV	B1	3.18±1.08	2.55±0.61	2.31±0.41	2.22±0.34	2.19±0.27	2.43±0.48
	B2	4.71±2.17	2.98±1.21	2.73±0.69	2.73±0.88	2.65±1.00	2.88±0.86
f (breaths/min)	B1	16±2	21±4	20±4	23±5	22±5	19±4
	B2	15±1	22±3	21±3	24±5	23±4	20±4
TV (L/breath)	B1	2.47±1.62	1.38±0.93	1.48±0.66	1.69±0.86	1.76±0.76	1.31±0.64
	B2	1.58±1.05	1.02±0.65	1.13±0.59	1.45±0.80	1.48±0.84	1.01±0.58

Note: *Indicates the 95% upper confidence interval (UCI) of PIF.

As listed in Table VI, to some degree, the MV, MIF, PIF, f, and TV during different activities measured by devices B1 and B2 agreed with each other. Duncan's grouping of MV, MIF, and PIF for B1 and B2 were performed (see Table VII) to further evaluate the agreement between devices B1 and B2. It was observed that groupings reported by B1 and B2 were almost in the same order. Specifically, the highest MV was reported around 35 L/min when subjects changing linen (CL). Unlike device A, the MV of PA, reported as 31 L/min, did not rank the lowest. For both MIF and PIF, the groupings of the six activities can be categorized into three groups: 1) PA; 2) CW and CL; 3) IV, V and NB. Specifically, PA ranked the highest, with the average MIF and PIF of 110 and 200L/min, followed by the activities of CW and CL, and the lowest MIF and PIF values were found during activities of IV, V and NB. Similarly, the subjects had to increase the PIF to breathe in enough air in a shorter inhalation time during the PA activity.

Table VII. Duncan's Groupings of MV, MIF, and PIF for Devices B1 and B2

Activity	MV		MIF		PIF	
	B1	B2	B1	B2	B1	B2
PA	A	BC	A	A	A	A
V	B	BC	C	C	C	D
IV	B	B	C	C	C	CD
CL	A	A	B	B	B	B
CW	A	A	B	B	B	BC
NB	B	C	C	C	C	D

During non-speech activities, the PIF/MV ratios reported by B1 and B2 were generally >3.14 (see Table VI), which was similar to that of devices A1 and A2. Under speech conditions, the PIF/MV was around 7, which was close to the ratios reported by device A. PIF/MV ratios > 6 have also been reported by other researchers (Holmér et al. 2007). A similar finding was seen in MIF/MV ratios: during non-speech activities, the MIF/MV ratios were slightly > 2 ; during the PA process, the MIF/MV ratio was around 4, which was significantly higher than the other non-speech activities. The reason may be attributed to the reduction of inhalation time during speech. It was noted that the PIF/MV and MIF/MV ratios during each activity reported by devices A and B were very close to each other, indicating a good agreement in measuring those ratios.

As can be seen in Table VI, the f during PA activity (15 breaths/min) was significantly lower than any other non-speech activities (20-24 breaths/min). As stated earlier, this lower value was caused by the extended exhalation time during speech and the longer breath cycle time. The TV among different activities can be categorized into the same three groups as the MIF and PIF, that is, 1) PA; 2) CL and CW; 3) IV, V and NB, with TV values of 2.0, 1.6, and 1.2 L/breath for each group (see Table VI). The TV reported by devices B1 and B2 were significantly higher than the values reported by devices A1 and A2, all of which were around 1 L/breath (see Table IV). This higher TV values could be the reason for the significantly higher MV, MIF and PIF measured by devices B1 and B2. Since there were significant differences in both TV and f , it was concluded that the increase of MV values measured by devices B1 and B2 was associated with simultaneous increase of TV and f , i.e., to achieve more air volume inhaled, the subjects breathe deeper and faster.

The variability of device B was evaluated by the Bland-Altman method, and the mean differences and 95% LoAs of MV, MIF and PIF between B1 and B2 were presented in Fig. 4. To better evaluate the variability of device B, the average measurements of B1 and B2 were divided into two levels with the upper limit flows of MV, MIF and PIF for device B (70, 140 and 220L/min, respectively). It was found that, even within the measurement range, the mean differences of MV, MIF and PIF between devices B1 and B2 were 6.9, 9.6, and 15.3 L/min, all of which were significantly higher than those of device A. It was concluded that device B had a significantly higher variability when compared with the device A; thus the former may not be applicable for characterizing HCWs' breathing flow in the real healthcare environment.

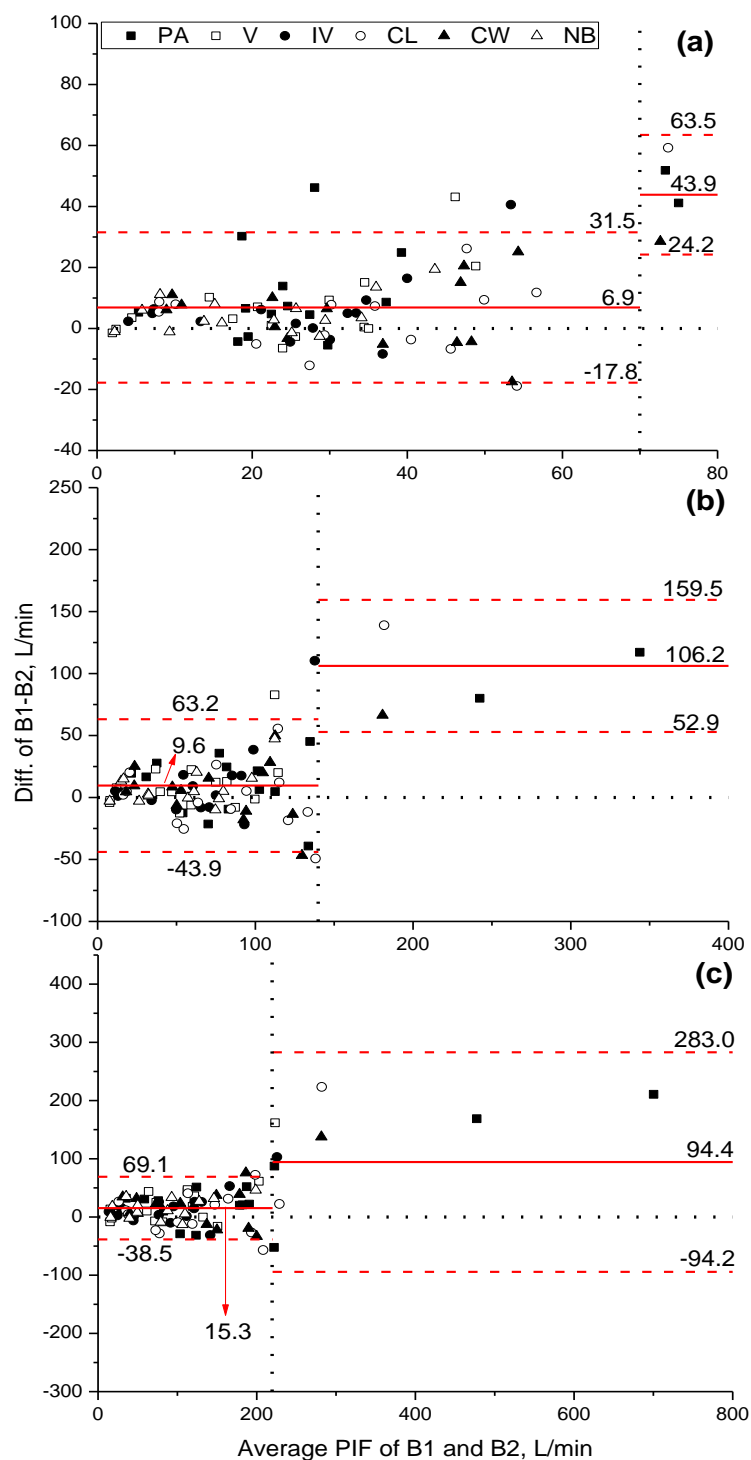


Fig. 4. Bland-Altman plots of MV (a), MIF (b) and PIF (c) for devices B1 and B2. The solid line indicates mean difference; the dashed lines indicate 95% LoAs; the horizontal dotted line represents mean difference of 0, the vertical dotted line represents the upper measurement limit of kdevice B.

Performance Comparison of Devices A and B

The average MV, MIF and PIF measured by device A were 23, 54, and 82 L/min with 95% CIs of 20-25, 48-60, and 72-92 L/min, respectively; the corresponding values reported by device B were significantly higher. This difference was mainly caused by the higher values of TV found with device B compared to that of A. The device A showed that TV stayed unchanged while f increased significantly with the increase of MV, i.e., human breathing was faster rather than deeper, whereas device B reported that TV and f simultaneously increased in response to the increase of MV. Both devices A and B confirmed that all six simulated healthcare work activities (see Table II) can be classified as light-moderate workload tasks, and that NIOSH PAPR standards development may consider lowering the 170 L/min minimum operational flow for loose-fitting PAPRs used in the healthcare environment.

The mean differences of MV, MIF, and PIF between devices A1 and A2 were 0.9, 1.3, and 2.8 L/min, which were much lower than the corresponding values (6.9, 9.6, and 15.3 L/min, respectively) presented by devices B1 and B2. Therefore, the conclusion was that the device A featured lower variability, suggesting that it could be a preferred choice for field applications, e.g., used in a field study of HCWs' breathing flow.

Limitations

There are a few limitations in this study. For example, neither device A nor B is a "gold standard" method. Through the variability comparison and agreement analysis between the two methods, it can only be determined which method is more reliable. In the repeated measurements design of this study, six tasks were selected to simulate the routine healthcare activities. Whether this selection agrees with the real healthcare practices needs to be further investigated.

CONCLUSIONS

Overall, the findings suggest that the personal breathing recording device from Manufacturer A produced less variability, thus is more applicable to investigate the respiratory characteristics of HCWs in a real hospital environment. The results obtained from this investigation can be considered for respirator certification, standards development, and respirator design to improve respiratory protection for HCWs.

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Disclaimer

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REFERENCES

- Bland JM, Altman DG (2003) Applying the right statistics: Analyses of measurement studies. *Ultrasound Obstet Gynecol* 22: 85-93.
- Bland JM, Altman DG (2007) Agreement between methods of measurement with multiple observations per individual. *J Biopharm Stat* 17: 571-582.
- Centers for Disease Control (2012) Workplace safety and health topics: Healthcare workers. Revised February 2012 <https://www.cdc.gov/niosh/topics/healthcare/>. Accessed 11 March 2018.
- Coffey CC, Lawrence RB, Campbell DL, Zhuang Z, Calvert CA, Jensen PA (2004) Fitting characteristics of eighteen N95 filtering-facepiece respirators. *J Occup Environ Hyg* 1: 262-271.
- Cohen HJ, Hecker LH, Mattheis DK, Johnson JS, Biermann AH, Foote KL (2001) Simulated workplace protection factor study of powered air-purifying and supplied air respirators. *Am Ind Hyg Assoc J* 62: 595-604.
- Cooper E (1960) A comparison of the respiratory work done against an external resistance by man and by a sine-wave pump. *Exp Physiol* 45: 179-191.
- Davidson CS, Green CF, Gibbs SG, Schmid KK, Panlilio AL, Jensen PA, Scarpino PV (2013) Performance evaluation of selected N95 respirators and surgical masks when challenged with aerosolized endospores and inert particles. *J Occup Environ Hyg* 10: 461-467.
- Grinshpun SA, Haruta H, Eninger RM, Reponen T, McKay RT, Lee SA (2009) Performance of an N95 filtering facepiece particulate respirator and a surgical mask during human breathing: two pathways for particle penetration. *J Occup Environ Hyg* 6: 593-603.
- He X, Grinshpun SA, Reponen T, McKay R, Bergman MS, Zhuang Z (2014a) Effects of breathing frequency and flow rate on the total inward leakage of an elastomeric half-mask donned on an advanced manikin headform. *Ann Occup Hyg* 58: 182-194.
- He X, Reponen T, McKay RT, Grinshpun SA (2013) Effect of particle size on the performance of an N95 filtering facepiece respirator and a surgical mask at various breathing conditions. *Aerosol Sci Technol* 47: 1180-1187.
- He, X, Reponen T, McKay R, and Grinshpun, SA (2014b) How does breathing frequency affect the performance of an N95 filtering facepiece respirator and a surgical mask against surrogates of viral particles? *J Occup Environ Hyg* 11(3), 178-185.
- Holmér I, Kuklane K, Gao C (2007) Minute volumes and inspiratory flow rates during exhaustive treadmill walking using respirators. *Ann Occup Hyg* 51: 327-335.
- Institute of Medicine (2015) *The Use and Effectiveness of Powered Air Purifying Respirators in Health Care*. McCoy, MA, Domnitz SB, and Liverman CT (eds.), Washington, DC: National Academies Press.
- International Organization for Standardization (2015): *Respiratory Protective Devices—Human factors. Part 1: Metabolic Rates and Respiratory Flow Rates (ISO/TS 16976-1:2015)*. Geneva, Switzerland: ISO Copyright Office.
- Kaufman JW, Hastings S (2005) Respiratory demand during rigorous physical work in a chemical protective ensemble. *J Occup Environ Hyg* 2: 98-110.
- Khoo KL, Leng PH, Ibrahim IB, Lim T (2005) The changing face of healthcare worker perceptions on powered air purifying respirators during the SARS outbreak. *Respirology* 10: 107-110.
- Lafortuna CL, Minetti AE, Mognoni P (1984) Inspiratory flow pattern in humans. *J Appl Physiol* 57: 1111-1119.
- Liverman CT, Larson EL (2011) Preventing transmission of pandemic influenza and other viral respiratory diseases: Personal protective equipment for healthcare personnel. Update 2010. National Academies Press. http://www.cdc.gov/niosh/docket/review/docket129A/pdfs/NIOSH-129-A_IOMreport.pdf. Accessed 11 March 2018.
- Mackey KR, Johnson AT, Scott WH, and Koh FC (2005) Over breathing a loose-fitting PAPR. *J Int Soc Resp Prot* 22(1/2): 1.
- Occupational Safety and Health Administration (1998) *Respiratory protection: Final rule*. U.S. Department of Labor, U.S. Government Printing Office, Washington, DC. Federal Register 63:1152-1300.

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- Occupational Safety and Health Administration (2006) Assigned Protection Factors: Final Rule, 2006, Department of Labor, OSHA, National Archives and Records Administration. Federal Register, 71(164): 50121-50192.
- Occupational Safety and Health Administration (2007) Guidance on preparing workplaces for an influenza pandemic. http://www.osha.gov/Publications/influenza_pandemic.html. Accessed 11 March 2018.
- Rengasamy S, Eimer BC, Shaffer RE (2012) Evaluation of the performance of the N95-companion: effects of filter penetration and comparison with other aerosol instruments. *J Occup Environ Hyg* 9: 417-426.
- Rengasamy S, Eimer BC, Szalajda J (2014) A quantitative assessment of the total inward leakage of NaCl aerosol representing submicron-size bioaerosol through N95 filtering facepiece respirators and surgical masks. *J Occup Environ Hyg* 11: 388-396.
- Roberge RJ (2008) Evaluation of the Rationale for Concurrent Use of N95 Filtering Facepiece Respirators with Loose-fitting Powered air-purifying Respirators during Aerosol-generating Medical Procedures. *Am J Infect Control* 36(2): 135-141.
- Roberge MR, Vojtko MR, Roberge RJ, Vojtko RJ, Landsittel DP (2008) Wearing an N95 respirator concurrently with a powered air-purifying respirator: Effect on protection factor. *Respir Care* 53: 1685-1690.
- Silverman L, Lee G, Plotkin T, Amory L, Yancey AR (1945) Fundamental factors in the design of protective respiratory equipment: inspiratory and expiratory air flow measurements on human subjects with and without resistance at several work rates. Department of Physiology, Harvard School of Public Health, Harvard University.
- Zhuang Z, Bergman MS, Eimer BC, Shaffer RE (2013) Laboratory face seal leakage evaluation of N95 filtering facepiece respirators against nanoparticles and "All Size" particles. *J Occup Environ Hyg* 10: 496-504.