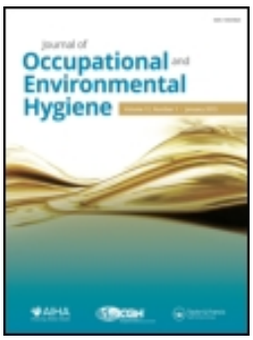

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Comparison of two quantitative fit-test methods using N95 filtering facepiece respirators

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ABSTRACT

Current regulations require annual fit testing before an employee can wear a respirator during work activities. The goal of this research is to determine whether respirator fit measured with two TSI Portacount instruments simultaneously sampling ambient particle concentrations inside and outside of the respirator facepiece is similar to fit measured during an ambient aerosol condensation nuclei counter quantitative fit test.

Sixteen subjects (ten female; six male) were recruited for a range of facial sizes. Each subject donned an N95 filtering facepiece respirator, completed two fit tests in random order (ambient aerosol condensation nuclei counter quantitative fit test and two-instrument real-time fit test) without removing or adjusting the respirator between tests. Fit tests were compared using Spearman's rank correlation coefficients.

The real-time two-instrument method fit factors were similar to those measured with the single-instrument quantitative fit test. The first four exercises were highly correlated ($r > 0.7$) between the two protocols. Respirator fit was altered during the talking or grimace exercise, both of which involve facial movements that could dislodge the facepiece.

Our analyses suggest that the new real-time two-instrument methodology can be used in future studies to evaluate fit before and during work activities.

KEYWORDS
Fit testing; real-time; respiratory protection

Introduction

The gold standard for assuring proper respirator performance is to conduct one or more workplace protection factor (WPF) study in a representative population of workers. A WPF study measures overall respirator performance in a given workplace for the duration of the workday while a subject performs their job. Such studies are expensive and difficult to perform in industrial settings; additional barriers make them almost impossible to conduct in healthcare settings.[1]

Respirator fit tests in the United States use a prescribed set of eight exercises: normal breathing, deep breathing, moving head side-to-side, moving head up-and-down, talking, grimacing, bending over, and normal breathing once more.[2] These exercises were derived from tasks performed in military and industrial settings.[3] There are no data, however, demonstrating that the fit factor measured in a laboratory setting using these eight exercises is relevant to or predictive of an individual's fit during actual wear in a workplace.

A few investigators have used a real-time methodology for measuring respirator fit that employs two particle count instruments to simultaneously measure particle number concentrations inside and outside a respirator facepiece second-by-second.[1,4] Hauge et al. recently used this approach to measure the fit of an N95 filtering facepiece respirator worn by eight registered nurses performing typical healthcare tasks in a simulated patient care room. They demonstrated that the protocol was feasible and their data suggested there was an association between each subject's initial quantitative fit factor using the traditional instrument and eight OSHA exercises and fit measured with the two-instrument method during simulated healthcare tasks.[1] The association was confounded, however, by the use of two different instrument protocols. Thus, the goal of this work was to determine conclusively if fit measured with the new real-time methodology is similar to that measured using the traditional method.

We describe here the results of experiments designed to demonstrate that the new real-time methodology produces similar fit factors as a traditional quantitative fit test

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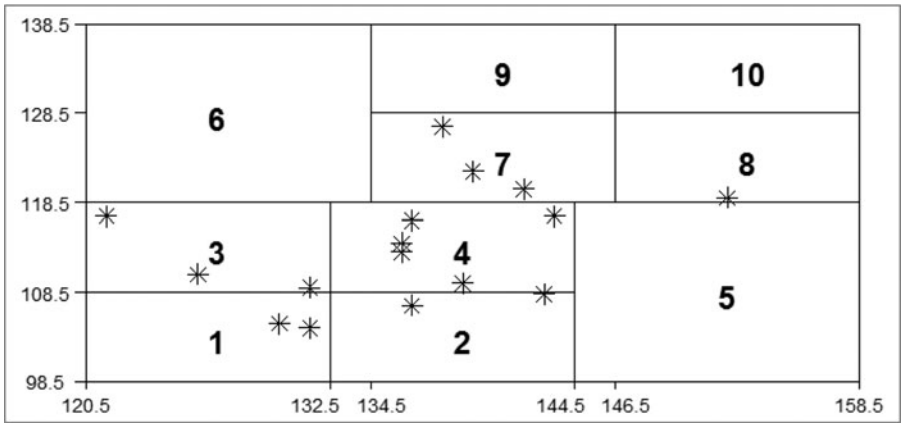

Figure 1. Bivariate cells by face length and width (mm) as determined by Zhuang et al.[10] and distribution of subjects' face length and width (indicated by stars).

for each of the eight fit test exercises as well as for the exercises combined. In addition, we explore in more detail the effect of wear time on respirator fit, the nature of fit for each of the exercises, and the effect of each exercise on overall fit.

Methods

Use of human subjects' approval was obtained from the University of Illinois at Chicago Institutional Review Board prior to recruitment (approval number 2013–1160).

Subject recruitment

The goal was to recruit at least 15 subjects with a range of face sizes and at least 3 subjects in cells 3, 4, 7, and 8 in the NIOSH bivariate panel (Figure 1). This number was selected as feasible in the time available for this project. These cells were selected because they would be the most representative of the U.S. population. Subjects were recruited using posted flyers and emails and screened by telephone or email survey using a preliminary questionnaire to assess health conditions and willingness to be clean shaven and refrain from smoking and drinking at least 60 min prior to a test. Subjects were scheduled for a one-hour time period. No compensation was offered.

Upon arrival each subject completed a written survey with questions similar to those used in screening, ensuring they had no respiratory or other health concerns that would make wearing a respirator difficult, did not experience claustrophobia, did not have facial impediments that would interfere with fit, were clean shaven, and were between 18 and 65. Subjects were also asked to confirm they had refrained from eating and smoking. Subjects not meeting these criteria were not tested further. Written informed consent was obtained for each subject.

Each subject's face length (menton sellion) and width (bizygomatic breadth) were measured using a sliding caliper (Model 104, Seritex, Tinton Falls, NJ) and spreading caliper (Model 106, Seritex, Tinton Falls, NJ), respectively. These measurements were used to determine each subject's cell in the NIOSH bivariate fit test panel.[5]

Experimental set-up

All fit tests were conducted in a test chamber consisting of a 5 ft (width) × 5 ft (length) × 9 ft (height) (1.5×1.5×2.7 m) portable tent (VUE Canopy, Canopy Max E-Z UP, Murrieta CA) with clear plastic sides and zipper access at all corners. Three salt aerosol generators (Model 8026, TSI Inc., Shoreview MN) and an ultrasonic humidifier (Model V5100NS, Vicks, Greensboro, NC) were used to generate particles and a floor fan was employed to maintain a steady uniform aerosol concentration inside the test chamber. Aerosol concentration as measured by a Portacount with N95 companion ranged from 1000–2500 p/cm^3.

Three TSI Portacount Plus (Model 8020, TSI, St. Paul, MN) with N95-Companion (Model 8095) instruments were used throughout the study: Portacount A was used to measure fit following the OSHA ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol and Portacounts B and C were used to measure real-time fit simultaneously inside and outside the respirator.[6] All pair-wise combinations of Portacounts were tested using a range of particle concentrations to ensure a similar (± 15%) and linear response.

Fit tests

The respirator was previously probed just in front of the mouth using the TSI probing tool (Model 8025-N95, TSI,

St. Paul, MN). A probed respirator was attached to 8-ft non-conductive Tygon tubing. The researcher ensured the respirator was donned correctly. A large binder clip attached to the subject's clothing was used to stabilize the tubing while ensuring enough slack for head movements. While wearing the respirator subjects sat still for 5 min to allow for any comfort adjustments and ensure proper fit during the experiment.

Once face size was measured, an N95 filtering facepiece respirator was selected (3M 1860 or 3M 1860s). Subjects began the experiment using the size thought to give the best fit. If, after the first fit test exercise, the measured fit factor was less than 100, the experiment was stopped and the other size respirator was used. If the second size respirator did not result in a fit factor greater than 100, the experiment was stopped and the subject was excluded from the study.

During each fit test, subjects performed the eight traditional exercises for 2 min each in the order mandated by OSHA (normal breathing, deep breathing, turning head side-to-side, moving head up-and-down, talking, grimace, bending over, and normal breathing).[2]

Traditional fit test instrument

A single CNC instrument was used to measure respirator fit as described in the OSHA ambient aerosol condensation nuclei counter protocol.[6] The instrument employs a switch valve to take alternating samples of ambient and inside-facepiece particle concentrations, with 5-sec purges after each ambient sample to ensure zero particles in the sampling tube prior to inside-facepiece sampling. Purge times were extended to 20 sec in this study to account for the longer 8-ft tube lengths, which were employed in preparation for later studies involving more strenuous healthcare tasks. The instrument software (TSI Fitplus, version 3.4, TSI, St. Paul, MN) was used to capture and record all measures of ambient and in-facepiece concentrations and calculated fit factors for each exercise; the displayed fit factors were also recorded manually.

Real-time fit test method

During the real-time fit test protocol, two Portacount instruments (Model 8020, TSI, St. Paul, MN) were used, one sampling particle concentrations inside the facepiece while the second simultaneously sampled particle concentrations in the ambient air just outside the facepiece. Proprietary software (3M Company, St Paul, MN) recorded second-by-second particle counts from each instrument simultaneously.

During the traditional fit test both sampling tubes were connected to a single Portacount instrument (A). For real-time measurements, the sampling tubes were moved to separate instruments (from Portacount A to B and from Portacount A to C for ambient and in-facepiece concentrations, respectively) to ensure the respirator faceseal was not modified. The same protocol was followed in reverse for tests beginning with two instruments.

Experimental protocol

Each subject completed two fit tests, one traditional and one using the new protocol, in sequence without removing or adjusting the respirator. The order in which the fit tests were performed was randomized. Subjects performed the same sequence of exercises for the same time periods during each of the two fit tests. Each set of exercises takes 15 min to complete; an entire experiment was completed in about 35 min.

Data analysis

For the traditional fit test, the instrument software assumes the data will be normally distributed and calculates two averages for each exercise: (1) for all data recorded for 15 sec of ambient concentration measurements taken before and after the exercise and (2) for all data recorded for 50 sec of inside-facepiece concentration measurements taken throughout the exercise. The software then reports and calculates a fit factor for each exercise by dividing the latter by the former. An overall fit factor is calculated by taking the harmonic mean of seven of the eight exercise fit factors. The grimace exercise is omitted because it is designed to purposefully break the seal of the respirator and produce a lower fit factor. The software records and reports only the fit factors for each exercise and for the seven exercises combined.[7]

Prior to and after each experiment side-by-side measures of ambient concentration were recorded to derive a correction factor to adjust for small differences between the two Portacounts (B and C) used in the real-time fit test. After each experiment, the real-time data from Portacount B were adjusted using the correction factor.

Real-time fit factors were calculated using second-by-second measures of ambient and inside facepiece concentrations recorded by the 3M software and transferred to Microsoft Excel spreadsheets for analysis. The 50 sec of mask sampling data were used to calculate a fit factor for each exercise by dividing the mean of the concentrations

outside the facepiece (C_{out}) by the mean of the inside facepiece concentrations (C_{in}) (Equation (1)). Data below the limit of detection (0.6 p/cm^3) were replaced with a concentration of 1 p/cm^3, to be consistent with the TSI software for the single instrument method:

$$FF = \frac{\bar{c}_{out}}{\bar{c}_{in}}. \quad (1)$$

The overall fit factor was calculated excluding the grimace exercise using equation (2):

$$Overall\ FF = \frac{n}{\frac{1}{FF_1} + \frac{1}{FF_2} + \ldots + \frac{1}{FF_n}} \quad (2)$$

where FF_i = fit factor for each exercise and i = {1, 2, … n} for the exercise number.

Statistical analysis and graph generation were done using RStudio® (Boston, MA; http://www.rstudio.com). Boxplots were used to explore data distributions by type of fit test, exercise, and sequence. Spearman rank correlation coefficients were generated to evaluate the relationship between the traditional and real-time fit test exercises. A repeated measure analysis of variance (ANOVA) was used to control for variability within subjects to determine the effect of time on the normal breathing. A Bartlett test was applied to the fit factors during all normal breathing exercises to test for differences in variance between repetitions.

Multiple linear regression was performed to identify with fit test exercises had the greatest influence on overall respirator fit for both the traditional as well as the real-time fit tests.

Results

Subjects

The study was conducted during February and March of 2014. Twenty-two subjects expressed interest, two subjects decided not to participate because there was no compensation offered. One subject was not located in Chicago and would not have been able to travel to participate. Nineteen subjects were successfully recruited to participate. All subjects kept their appointments but 3 were rejected from participation because a good respirator fit could not be established. Sixteen subjects (ten female and six male) successfully completed the experimental protocol. The subjects' face sizes placed them in five of the ten NIOSH bivariate panel cells: 1 (two subjects), 3 (four subjects), 4 (six subjects), 7 (three subjects), and 8 (one subject) (Figure 1).

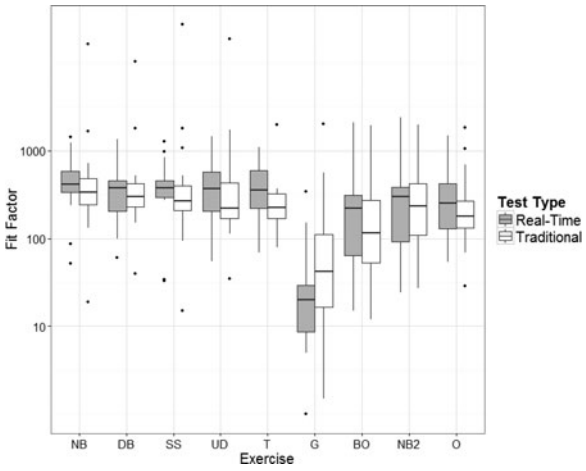

Figure 2. Real-time vs. traditional fit factors by exercise and for all exercises combined (n = 16) (NB – Normal Breathing; DB – Deep Breathing; SS – Head Side-to-Side; UD – Head Up-and-Down; T – Talking; G – Grimace; BO – Bend Over; NB2 – Normal Breathing 2; O – Overall).

Comparing two protocols

The 16 subjects had a similar distribution of fit factors under either protocol for each exercise and for all exercises combined, with the grimace showing the lowest fit factor and the largest difference between the two protocols (Figure 2). The two tests were highly correlated ($r \approx 0.7$) for the first four exercises and not at all correlated ($r < 0.1$) for the last three exercises (grimace, bending over and the second normal breathing). The overall fit factor for the two tests was moderately correlated ($r = 0.5$) (see Table 1).

A paired t-test indicated no significant differences between the fit factors from the two protocols for each exercise and for all exercises combined (p-values ranged from 0.19–0.93) (see Table 2).

Effect of time on fit

Boxplots comparing fit factors by test sequence (first vs. second) (Figure 3) indicate similarities in both median and range for the first five exercises, as was observed

Table 1. Correlation coefficients comparing real-time fit factors to traditional fit factors (n = 16).

Exercise	Spearman's r	p-value
Normal Breathing	0.685	0.003
Deep Breathing	0.762	0.001
Side-to-Side	0.718	0.002
Up-and-Down	0.720	0.002
Talking	0.422	0.117
Grimace	0.031	0.904
Bend Over	0.071	0.795
Normal Breathing 2	0.062	0.826
Overall	0.469	0.067

Table 2. Paired t-test comparing fit factors measured during exercises using the real-time and traditional methods.

Exercise	p-value
Normal Breathing	0.36
Deep Breathing	0.33
Head Side to Side	0.33
Head Up and Down	0.36
Talking	0.85
Grimace	0.19
Bend Over	0.86
Normal Breathing 2	0.93
Overall	0.90

when comparing the two protocols without respect to sequence (Figure 2). The highly positive and statistically significant correlations between fit factors measured by the two protocols for the first four exercises (ranging from 0.80 to 0.93 with p-values < 0.016) indicate that the fit test sampling protocols are similar (see Table 3).

A comparison of boxplots of the fit factors for the four normal breathing exercises, for all data from the two fit test protocols combined, shows that the first three repetitions are almost exactly alike with respect to medians and variance (Figure 4). The fourth repetition, which follows the second grimace exercise, shows a large increase in variance. Repeated measures ANOVA indicated, however, that none of the mean fit factors during normal breathing are significantly different from any of the others (p-value $= 0.275$); a Bartlett test found that the variance in at least one repetition is significantly different from the others (p-value < 0.001).

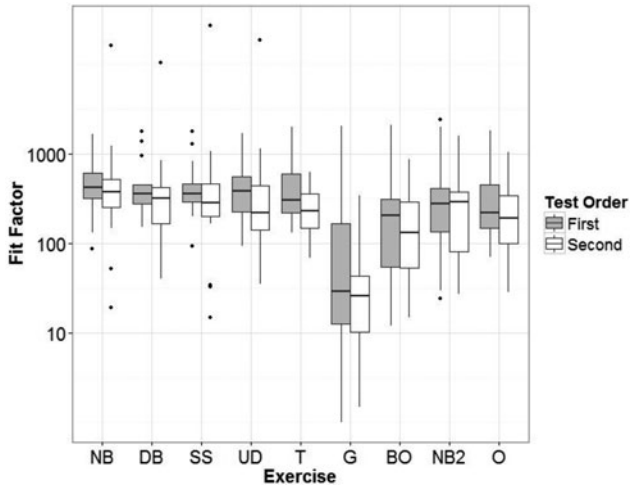

Figure 3. First fit test vs. second fit test by exercise by exercise and for all exercises combined (NB – Normal Breathing; DB – Deep Breathing; SS – Head Side-to-Side; UD – Head Up-and-Down; T – Talking; G – Grimace; BO – Bend Over; NB2 – Normal Breathing 2; O – Overall).

Table 3. Correlation coefficients by time (n = 8).

	Traditional then Real-Time		Real Time then Traditional	
	Spearman's r	p-value	Spearman's r	p-value
Normal Breathing	0.93	<0.001	0.80	0.016
Deep Breathing	0.84	0.009	0.81	0.014
Head Side-to-Side	0.91	0.001	0.88	0.004
Head Up-and-Down	0.92	0.001	0.87	0.005
Talking	0.74	0.034	0.64	0.120
Grimace	− 0.04	0.926	0.29	0.485
Bend Over	− 0.05	0.905	0.33	0.429
Normal Breathing 2	− 0.37	0.364	0.24	0.571
Overall	0.22	0.598	0.95	<0.001

Effect of exercise on fit

A step-wise multiple linear regression analysis was conducted to identify exercises with the greatest influence on overall fit (see Table 4). For the traditional fit test protocol the deep breathing, head side-to-side and bending over exercises were all significant variables in the model. The second normal breathing exercise was included in the model because it approaches significance. The real-time protocol showed bending over and talking exercises had the greatest influence on overall fit.

Discussion

Methodology development is crucial for the continued advancement of science. Every new method requires validation to the current, gold standard, in order to verify and confirm its results. This experiment takes a novel real-time respirator fit methodology and successfully confirms that it produces results similar to traditional, currently approved, OSHA fit test methods.

As expected, we demonstrated that the new real-time two-instrument method measures fit factors equivalent

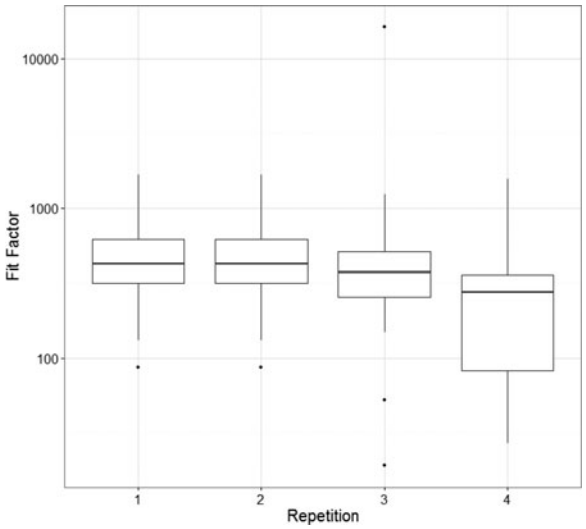

Figure 4. Normal breathing distribution by order performed.

Table 4. Results of step-wise multiple linear regression analysis predicting overall fit factor by exercises for (a) traditional fit test and (b) real-time fit test methods.

Exercise	Coefficient	P-Value
Traditional Fit Test		
Intercept	−16.85	0.422
Deep Breathing	0.49	0.002
Head Side-to-Side	−0.15	0.005
Bending Over	0.50	0.001
Normal Breathing 2	0.14	0.066
Real-Time Fit Test		
Intercept	29.91	0.44
Talking	0.55	<0.001
Bending Over	0.33	<0.001

to those measured with the traditional single-instrument quantitative fit test protocol. This was clearly illustrated by the fact that the first four exercises had almost identical fit factors when comparing the two protocols directly or when examining the data by testing order (see Figure 2).

Our analyses suggest that respirator fit is altered during either the talking or grimace exercise, both of which involve facial movements that could dislodge the facepiece. However, the manner in which these exercises influence fit is not consistent, which was only apparent when we compared the data by test order (see Figure 3).

Our test-order analyses also suggest that after the first talking or grimace exercise, regardless of protocol, respirator fit returns to its initial level. After the second talking or grimace exercise, however, the respirator does not re-seat in the same manner (see Table 2). For some subjects the respirator fit improved during the second test while for others it deteriorated. That this happened for either protocol indicates that this phenomenon is associated either with wear-time in general or more specifically due to inconsistent re-sealing following the talking or grimace exercise, or perhaps a combination of these variables.

In linear regression models, bending over was the only exercise that predicted overall fit in either the traditional or new fit test protocols. Deep breathing, head side-to-side and talking are also highly predictive of overall fit for at least one of the protocols. These findings are similar to those of Crutchfield et al., who found in a study with 14 subjects that talking and bending over were most likely to cause leaks in an elastomeric or full-facepiece respirator.[8] Richardson et al. found similar results in a study of 50 fit test-pairs examining how well a faster fit test protocol predicts respirator fit. The exercises included in this faster fit test were bending over, talking, head side-to-side, and head up and down.[9] Richardson et al. determined that performing each of these exercises for 30 sec results in a fit factor similar to the traditional OSHA QNFT.[9] Our study found the same exercises to be most predictive of overall fit.

To our knowledge this is the first study comparing repeated fit tests without re-donning. As well, few studies have examined the effect of wear-time or exercise on long-term respirator fit. Hauge et al. evaluated respirator fit in the context of three simulated healthcare-related work scenarios with eight subjects using the real-time methodology[1] and found the simulated workplace protection factors measured for the third scenario were significantly different from the first and second scenarios, suggesting that wear-time or multiple respirator dislodgements (or both) may be important to on-going respirator fit. These investigators were not able to explore the relationship between traditional and real-time fit factors due to software limitations.

In retrospect, the grimace exercise should have been excluded from the experimental protocol. This exercise is not used in the calculation of a fit factor and has an unpredictable effect on fit that introduces a source of unnecessary variability to the comparison of the fit testing protocols. Other limitations are the small number of subjects and the lack of subjects in all cells of the bivariate panel. More subjects in more cells would expand the generalizability of these findings.

It was observed during this set of experiments that there is some moisture buildup on the sampling tube measuring inside facepiece concentrations. The relationship between the two Portacounts used for the real-time methodology changed over time; after the experiment the inside facepiece Portacount measurements were lower than at the start. It is assumed that moisture in the tube results in particle collection and loss to instrument measurement. The time at which such particle loss occurs is not easy to determine, thus the line of best fit between the initial and the final sets of data was used to derive a correction factor between the two instruments.

A real-time sampling method offers important advantages over the traditional single-instrument approach. There is great interest in understanding how respirators perform over time in real-world workplace settings. In many instances, however, workplace conditions or sampling requirements preclude the measurement of workplace protection factors. It has been proposed that laboratory-based scenarios comprising multiple donnings or realistic work tasks might be used to measure a simulated workplace protection factor. The real-time methodology also allows exploration of respirator performance in environments where traditional WPF methods cannot be used, such as environments like healthcare settings where the ambient particle concentration is too low for full-shift gravimetric sampling.

The importance of novel methodology for real-time analysis of respirator fit is crucial to the future of respirator usage. Methods which can detect, instantaneously, and inform the user when a respirator is malfunctioning in the field would be an example of where the future of real-time methods lies.

This new real-time methodology will be used in future healthcare SWPF studies, in which simulated healthcare tasks will be performed in a laboratory setting to measure and predict respirator fit. In future work, by overlaying concentration data on top of video, we plan to use real-time data to determine specific tasks or head motions that cause a healthcare respirator to fail.

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