Assessment of a Novel Low-Cost Personal Respirator Evaluation Device

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ABSTRACT

Background: Throughout the COVID-19 pandemic, respirators and masks have been recommended, and in many instances mandated, across the globe. The National Institute for Occupational Safety and Health (NIOSH) is the main regulatory agency for respirators in the United States. Currently, the TSI 8130A and the ATI 100Xs machines are utilized for respirator filtration and resistance testing, but both are costly and valued upwards of U.S. $100,000.

Objective: The goal of this study was to develop a low-cost respirator evaluation mechanism (LREM) to evaluate respirators as well as masks and other materials for filtration efficiency (FE), inhalation resistance (IR), and exhalation resistance (ER). The aim of this mechanism is to support the development of innovative and alternative respirator and mask designs and materials with an inexpensive and more accessible testing device.

Methods: The methods and design for the LREM were based on U.S. 42 CFR Part 84 Subpart K and the corresponding standard testing procedures for air-purifying respirators published by NIOSH. The LREM itself is constructed from available components and functions to deliver sodium chloride (NaCl) aerosols in a stream of airflow to challenge a respirator or mask sample. A variety of respirators, masks, and materials were tested on both the LREM and an ATI 100Xs to assess how the LREM compares to one of the current evaluation devices.

Results: Overall, the LREM offers promise as an accessible and low-cost testing option. The LREM can accurately determine the pass/fail status of the N95 filtering facepiece respirators (FFRs) samples tested for both IR and FE based on NIOSH criteria. For all respirators, masks, and materials tested, the LREM and ATI 100Xs both show similar performance trends as seen by rankings of sample performance.

Conclusions: The LREM was constructed for approximately 6% the cost of current respirator testing gold standards. The LREM could serve as a first pass testing method done before official respirator testing (e.g. per NIOSH mandated testing) and can be particularly useful in the development of innovative respirators and masks or in testing alternative materials for each.

Keywords: COVID-19, respirator, mask, respirator testing, filtration efficiency, inhalation resistance, exhalation resistance.

INTRODUCTION

On March 11th, 2020, the World Health Organization (WHO) officially declared COVID-19 as a pandemic (WHO, 2020). Since then, there have been over 600 million cases and over 6 million deaths globally (Johns Hopkins University, 2022). The world has drastically changed since this announcement, and we now have a better understanding of the disease itself and prevention measures. Overall, SARS-CoV-2, the virus which causes COVID-19 infection, primarily spreads through tiny respiratory droplets that are released to the ambient environment when an infected individual coughs, sneezes, speaks, sings, or breathes (WHO, 2021) (CDC Science Brief, 2021). This transmission largely occurs when individuals are in close contact with each other, known as short-range aerosol transmission, or even through larger droplets that directly contact one's eye, nose, or mouth, known as droplet transmission (WHO, 2021).

Given what is known about the spread of COVID-19, masks have been recommended, and in many instances mandated, across the globe (CDC Science Brief, 2021) (CDC How coronavirus spreads, 2021) (CDC, 2022). Masks have primarily been intended to be used as a means of source control, by containing and reducing the emission of potential virus-laden droplets from the wearer (CDC Science Brief, 2021) (CDC, 2022). Many observational studies have also supported the use of masks, particularly in reducing community spread (CDC Science Brief, 2021). One study observed early on during the pandemic that in the U.S. in states where mask mandates were implemented, there was a 2% decline in the daily COVID-19 case growth rate after 21 days (Lyu, 2020). Another study observed that the estimated case rate per 100,000 decreased by 0.08 in U.S. counties with a mask mandate compared to counties without the mandate, where the case rate increased by 0.11 (Van Dyke, 2020).

While source control is the primary aim of masks, respirators such as N95 filtering facepiece respirators (FFRs) can provide higher levels of wearer protection (CDC, 2022). N95 FFRs are designed to provide greater than 95% protection against 0.3 micrometer (μm) sized particles (CDC Respirator FAQs, 2021). Studies have shown that N95 FFR use has been associated with fewer viral infections in healthcare workers compared to surgical masks (Collins, 2021). N95 FFRs have also been demonstrated to reduce the risk of SARS-CoV-1 and 2 viral infection by 17% compared to a population wearing surgical masks (Collins, 2021). Another study showed that fit-tested N95 FFRs significantly lowered the amount of a virus reaching the wearer's face compared to a no-protection control and that fit-test passed N95 FFRs performed better than N95 FFRs which did not pass this testing (Landry, 2022), highlighting the importance of proper fit in respirator protection provided to the wearer.

The National Institute for Occupational Safety and Health (NIOSH) is the main regulatory agency for respirators in the U.S. (Schall, 2021). These regulations are outlined in U.S. 42 CFR Part 84 Approval of Respiratory Protective Devices (Code of Federal Regulations, 2021). Subpart K specifically outlines requirements for air-purifying respirators and focuses on protection against particulate matter (PM) (Code of Federal Regulations, 2021).

NIOSH standards are meant to represent a worst-case scenario, particularly with regard to filtration testing (Schall, 2021). This requires eliminating the natural attraction that occurs from filter media and particles being oppositely charged, thus making it harder for the filter to trap particles (Schall, 2021). Testing therefore requires that particles are at a neutral electrostatic charge. The 0.3 μm sized particles in mass median aerodynamic diameter (MMAD) that define the performance of air-purifying particulate respirators with N95 level of protection have also been shown to be the most challenging to filter (Schall, 2021) (3M Company, n.d.). NIOSH standards thus require testing with neutralized sodium chloride (NaCl) aerosols with a count median diameter (CMD) of 0.075 ± 0.020 μm and a geometric standard deviation (GSD) not exceeding 1.86 (electrical mobility diameter as determined with a scanning mobility particle sizer or equivalent) delivered in a flow of air at 85 ± 4 (± 1.4 for resistance testing) liters per minute (lpm) (Code of Federal Regulations, 2021). This CMD value specified by NIOSH will result in the appropriate

MMAD, making them equivalent (Finlay, 2020). There are also three main requirements for air-purifying particulate respirators with N95 level of protection that must be met to obtain NIOSH certification. These are a maximum allowable inhalation resistance (IR) of 35 millimeters of water (mmH_2O), a maximum allowable exhalation resistance (ER) of 25 mmH_2O, and a filtration efficiency (FE) greater than 95% (Code of Federal Regulations, 2021).

Early on during the pandemic when N95 FFRs were in short supply, KN95 respirators provided an alternative means of protection. KN95 respirators must meet the Chinese regulations outlined in GB2626-2019 Respiratory Protection - Non-Powered Air-Purifying Particle Respirator (Standardization Administration of China, 2019). This standard is similar to the NIOSH standard and also requires testing with NaCl aerosols at a CMD of 0.075 ± 0.020 µm and a GSD not exceeding 1.86. At 85 ± 4 (± 1 for resistance testing) lpm flow, KN95 respirators must provide greater than 95% FE and less than 210 Pascals (Pa) of IR and ER (Standardization Administration of China, 2019). Resistance across the respirator is correlated with the ease of breathability for both standards.

The main evaluation tools used for respirator testing are the TSI 8130A (TSI Incorporated, Shoreview, MN) and the ATI 100Xs (Air Techniques International, Owings Mills, MD), both of which operate per U.S. 42 CFR Part 84, GB2626-2019, and other international regulatory standards (TSI Incorporated, 2022) (Air Techniques International, 2022). These systems are quite costly however and are valued upwards of U.S. $100,000. In particular, the laser photometer systems utilized in each machine to measure particulate concentrations can cost between U.S. $20,000 to $30,000. In addition, the lead times for this equipment can be multiple months and finding facilities which offer this testing can be difficult and costly.

Interest has also been given towards developing more innovative respirator and mask designs to address current limitations and better prepare for future diseases and pandemics. These new designs will require extensive testing throughout the design process, which can end up being costly and timely. This leads to the overall objective and goal of this study, which was to develop a low-cost respirator evaluation mechanism (LREM) intended to evaluate both respirators and masks as well as other materials used in lieu of formal respirators and masks. The LREM itself is constructed with available components that can be replicated in a laboratory setting to evaluate FE, IR, and ER. The aim of this mechanism is to support the development of innovative respirator and mask designs and use of alternative materials with an inexpensive and more accessible test method.

METHODS

LREM Design

The methods and design of the LREM were based on U.S. 42 CFR Part 84 Subpart K and the corresponding standard testing procedures for air-purifying respirators published by NIOSH (Code of Federal Regulations, 2021) (NIOSH Determination of Exhalation Resistance, 2019) (NIOSH Determination of Inhalation Resistance, 2019) (NIOSH Particulate Filter Efficiency, 2019). For this study, focus was given to evaluate FE and IR. Major components of the LREM include a TSI 3076 Aerosol Generator (TSI Incorporated, Shoreview, MN), a pressure regulator (capable of 35 pound-force per square inch, gauge (psig)), a drying apparatus with silica beads (Thermo Fisher Scientific, Waltham, MA), a chamber housing the respirator or sample, two Sensirion SPS30 PM sensors (Sensirion, Stäfa, Switzerland), a differential pressure sensor (DLLR-L10D-E1BD-C-NAV7) (All Sensors Corporation, Morgan Hill, CA), an Arduino Mega 2560 (Arduino, Ivrea, Italy), a bacterial viral filter (to limit and prevent NaCl aerosols from reaching the flow controller), and lastly, an Omega FMA5542A Flow Controller (Omega Engineering Inc., Norwalk, CT) working under vacuum. The overall setup was constructed for

under $6,000 and can be viewed in Figure 1. A bill of materials for the major components can be found in Supplemental Table I.

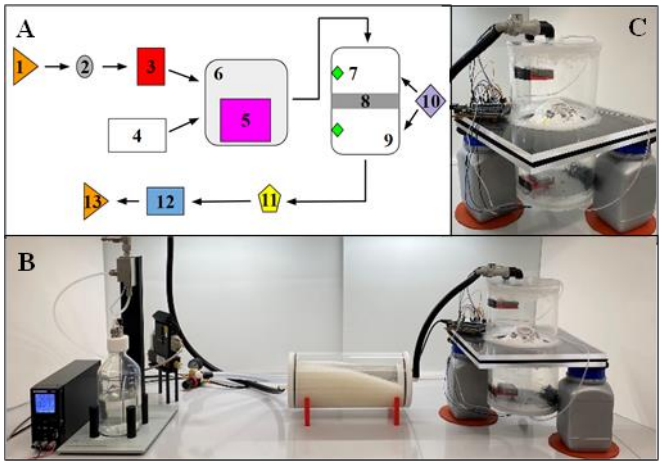

Figure 1. A schematic of the LREM design with the wall supply air source (1), pressure regulator (2), aerosol generator (3), ambient air (4), drying apparatus (5), mixing chamber (6), particulate matter (PM) sensors (7), mask/sample (8), respirator/sample chamber (9), differential pressure sensor (10), bacterial viral filter (11), flow controller (12), and vacuum wall supply (13) (A). The actual LREM setup (B) and a detailed view of the respirator chamber (C).

Airflow

Airflow for the LREM was supplied via the laboratory's vacuum wall source (expected to be clean and filtered) and was controlled by the Omega FMA5542A flow controller. This flow rate was constrained by the vacuum wall supply and pressure drop across the flow controller, limiting flow rates to 30 lpm. To characterize the effect of flow rate on respirator performance, 3M 8210 N95 FFRs (n=3) (3M Company, Maplewood, MN) were subject to different flow rates from 10 to 85 lpm on an ATI 100Xs. A Tukey's range test was then performed for FE and IR values across multiple flow rates to determine statistical significance.

Particle Size

Aligning with NIOSH standards, this setup utilized NaCl aerosols with a geometric mean of 0.075 µm and a geometric standard deviation of 2.00 (geometric mean equivalent to CMD in a normal distribution (TSI Incorporated, 2012)). To achieve this, a 0.0004 grams per cubic centimeter (g/cm^3) NaCl solution was prepared using distilled water as per the TSI 3076 Aerosol Generator manual (where particle size distributions were said to be measured with a Scanning Mobility Particle Sizer Spectrometer (TSI 3936L85 SMPS)) (TSI Incorporated, 2013).

Aerosol Detection

The Sensirion SPS30 PM sensors used with the LREM operate within a mass concentration range from 0 to 1,000 micrograms per meter cubed (Sensirion, 2020). These sensors measure via light scattering and can detect particles in the mass concentration size range of 0.3 to 10.0 µm (MMAD) (Sensirion, 2020). Two sensors were used in the setup and FE was calculated based on the following

equation, where upstream particle count is measured before the aerosol stream passes through the sample and downstream particle count is measured after:

$$FE(\%) = \left(\frac{Upstream\ Particle\ Count\ - Downstream\ Particle\ Count}{Upstream\ Particle\ Count}\right) * 100$$

Resistance Measurements

The differential pressure sensor (DLLR-L10D-E1BD-C-NAV7) used in the setup has an operating range of ± 254 mmH_2O (max error 0.25% full scale) (All Sensors, n.d.). This sensor had two ports to measure differential pressure across the respirator, mask, or sample in question.

Respirator/Sample Chamber Construction

During testing with the LREM, the test sample is housed in an air-tight chamber. This chamber was constructed using acrylic parts and separated into a top and bottom half. Two foam sheets were utilized to provide an airtight seal when in compression due to the vacuum flow. The sample would then sit in between the two foam sheets and halves of the chamber. The chamber contained a combination of quick disconnect and barbed fittings to allow for aerosol and airflow tubing connections in and out of the chamber. The PM sensors were mounted on 3D printed ledges on both the top and bottom halves of the chamber. Ports were also present on each half of the chamber to allow for tubing connections for the differential pressure sensor. A detailed view of the chamber is displayed in Figure 1C.

Drying Apparatus Construction

It was necessary to dry the aerosols before they challenged the respirator per NIOSH standards (Code of Federal Regulations, 2021) (NIOSH Particulate Filter Efficiency, 2019). A drying apparatus was thus constructed using acrylic and silica gel held in place with a wire mesh. This design was similar to that of the TSI 3062 Diffusion Dryer (TSI Incorporated, Shoreview, MN) which was specified in the TSI 3076 manual (TSI Incorporated, 2013).

Samples Evaluated

Respirators, masks, and other materials were evaluated on both an ATI 100Xs (Supplemental Figure 1) and the LREM at 30 lpm. These samples were 3M 8210 N95 FFRs (3M Company, Maplewood, MN) (n=20 for the ATI 100Xs, 20 for the LREM), Shanghai Tenry Pharmaceutical Co. Ltd KN95 respirators (Shanghai Tenry Pharmaceutical Co. Ltd, Shanghai, China) (n=10,10), Lutema M95c children's masks (Lutema, San Diego, CA) (n=5,5), Halyard H100 sterilization wraps (Halyard Health, Alpharetta, GA) (n=7,7), Medline heavyweight sterilization wraps (Medline Industries, Northfield, IL) (n=6,6), Hanes reusable cotton masks (Hanes, Winston-Salem, NC) (n=10,10), VPAYI reusable cloth masks with PM2.5 filter inserts (VPAYI, Amazon, Seattle, WA) (n=5,5), Parquet polyester masks (Parquet, Amazon, Seattle, WA) (n=6,6), neck gaiter material (Finvizo, Amazon, Seattle, WA) (n=4,4), and cloth bandanas (Boolavard, Amazon, Seattle, WA) (n=3,3). These specific respirators, masks, and materials represent common respiratory protective devices used throughout the pandemic over a range of performance and can be viewed in Supplemental Figure 2.

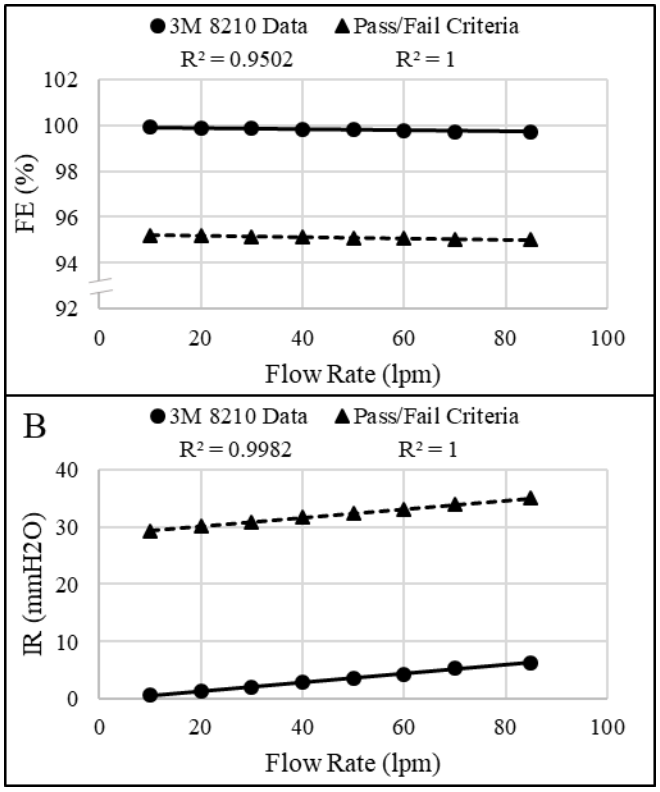

Figure 2. The average FE of 3M 8210 N95 FFRs (n=3) plotted against flow rate (A) and IR plotted against flow rate for the same FFRs (B). Linear trendlines were fit to the data and lines with the same slope were then plotted at current NIOSH N95 FFR criteria at 85 lpm (95% for FE, 35 mmH_2O for IR). Using these new lines with the same slope, the corresponding pass/fail criteria for N95 FFRs at 30 lpm were determined.

Samples were tested as received from the packaging with separate packs tested on either the ATI 100Xs or the LREM. For the neck gaiter samples, which came in a pack of four, separate sections from each individual gaiter were tested on both the LREM and ATI 100Xs. The cloth bandanas were in a pack of 3 and separate sections from each were tested on both the ATI 100Xs and LREM. Samples tested across both setups matched lot and/or production numbers.

Environmental Conditioning

All samples were environmentally conditioned per NIOSH standard testing procedures prior to testing in order to have a consistent basis for comparison and evaluation. Conditioning occurred for 25 ± 1 hours (h) at 38.5 ± 2.5℃ and 85 ± 5% relative humidity. The samples were then sealed in a gas tight container and tested within 10 h (Code of Federal Regulations, 2021) (NIOSH Particulate Filter Efficiency, 2019). The only samples that differed from this protocol were the Shanghai Tenry Pharmaceutical Co., Ltd KN95 respirators which followed the GB2626-2019 standard. This protocol differed from NIOSH protocol and called for a three-step conditioning process beginning with the respirators being exposed to 38.5 ± 2.5℃ and 85 ± 5% relative humidity for 24 ± 1 h. This was followed by conditioning for 24 ± 1 h in a 70 ± 3℃ dry environment and then another 24 ± 1 h at -30 ± 3℃ (Standardization Administration of China, 2019).

Sample Testing and Data Collection

Following environmental conditioning, the samples were mounted on aluminum sheets using hot glue to create an airtight seal (Supplemental Figure 3A). For the traditional masks, those labeled and sold as protective face coverings, the aluminum sheets had an elliptical opening. For the other materials (the H100 sterilization wraps, heavyweight sterilization wraps, neck gaiters, and cloth bandanas), the samples were mounted on aluminum sheets with a square opening of 100 centimeters squared (cm^2) (Supplemental Figure 3B). This area was chosen to simplify the test area for these alternative materials. A typical N95 FFR has a surface area of 150 cm^2, which corresponds to a face velocity of 10 centimeters per second (cm/s) at the 85 lpm specified by NIOSH (LaRue, 2021). To account for the 100 cm^2 area and keep the 10 cm/s face velocity, the flow rate for official NIOSH testing would thus need to be adjusted to 60 lpm. For the LREM, however, testing was limited to 30 lpm.

Testing on the ATI 100Xs began with a gravimetric test to calculate aerosol concentration and to verify that it is within the expected range. The ATI 100Xs also performs a penetration calibration and light scattering chamber (LSC) calibration in order to confirm airflow and aerosol detection. A negative control of unobstructed flow as well as a positive control of a 3M 8200 N95 FFR (3M Company, Maplewood, MN) that is known to pass were then tested to confirm system performance. For each of the tested samples, filter testing mode on the system was used. Here, the sample was challenged with aerosols for 60 seconds (s), followed by a 10 s sampling time. These times were chosen to provide enough time for the aerosol concentration to reach steady state (determined at the time when the slope of percent penetration over time reached zero during unobstructed flow, also known as the stationary point). At the end of this time, the ATI 100Xs output a percent penetration (which was then manually converted to FE) and an IR value. These values were then recorded and saved to a PC using serial communication.

On the LREM, the pressure sensor and PM sensors were connected to an Arduino Mega 2560. Arduino sketches along with their corresponding libraries that were written for the respective sensor elements (the pressure sensor and PM sensors) were found on GitHub. These sketches worked with their respective sensors to communicate between the sensors and the PC while controlling factors such as output rate. These sketches were then combined into one and minor edits were made to simplify the sketch. The pressure sensor operated via I^2C communication while the PM sensors used UART communication. The final code and citations are in the supplemental material.

To confirm that the LREM was air-tight, the sample chamber and tubing connections first underwent leakage testing. This test used an uncut aluminum sheet across the middle opening of the chamber to block airflow and create a seal once 10 lpm suction flow was applied. Suction was then shut off and the pressure in the system was observed to detect any signs of a leak and pressure change greater than 0.635 mmH_2O (based on pressure sensor's capabilities).

Daily baseline pressure was assessed and documented prior to initiating. Baseline pressure was measured with 30 lpm unobstructed air flow through the LREM. After steady state was reached at the stationary point for pressure over time (100 s), 60 s of data was recorded. These pressure values at steady state were averaged and used to set the baseline value on the Arduino sketch. Following this, the performances of the PM sensors were verified. This was done by having aerosols flow through the setup unobstructed at 30 lpm. After 100 s to reach a steady state of particle counts and FE measurements, 300 s worth of data was recorded and the average percent difference between the two sensors was found.

Once these pre-testing steps were complete for the LREM, sample testing began. An unobstructed flow condition was used as a negative control and a 3M 8210 N95 FFR that passed on the ATI 100Xs was used as a positive control. Here, the aerosols challenged the sample for 110 s in total. This time interval provided enough time for the aerosol concentration and various sensor measurements to reach steady state (100 s) while also matching the sampling time on the ATI 100Xs (10 s). The FE and IR were then recorded at the end of this time. Data for the LREM was recorded using a LabView Virtual

Instrument file (VI). Flow rate, FE, and IR, as well as more detailed particle count data were recorded at 2 s intervals and displayed on the PC using the VI. This data was then exported to Excel.

Venturi Setup

A VDF 200 flow venturi vacuum pump (Bimba Ltd., University Park, IL) has also been incorporated into the LREM setup. This venturi setup used positive pressure to generate a suction flow capable of reaching 85 lpm in accordance with NIOSH standards (Code of Federal Regulations, 2021). The venturi setup was unable to reach 85 lpm when used in line with the flow controller, and thus, a pneumotachometer (Model 4830, Hans Rudolph Inc., Shawnee, KS) was used to measure a resistance that could be related to flow rate. Initial testing was conducted with 3M 8210 N95 FFRs (n=10 for the ATI 100Xs, 10 for LREM).

Statistical Analysis

Following data collection, statistical analyses were performed. Data collected on each testing system was first subject to a Kolmogrov-Smirnov test (α=0.05) to confirm the normality of the distribution. Following this, a generalized extreme Studentized deviate test (α=0.05) was performed to determine outliers in the dataset. Hypothesis testing was performed using a student's t-test (two-tailed, unequal variance, α=0.05) to test for statistical significance between the sample testing on each setup.

RESULTS

Effect of Lower Flow Rate on Respirator Performance

As the LREM is run at a lower flow rate (30 lpm versus 85 lpm), the correlating pass/fail FE and IR for air-purifying particulate respirators with N95 level of protection were determined using N95 FFRs which already met NIOSH standards. The FE and IR at 30 and 85 lpm were found to be statistically significant. To determine the corresponding NIOSH pass/fail criteria at 30 lpm, the average IR and FE from the 3M 8210 N95 FFRs were plotted against flow rate and a linear trendline was fitted to the data (Figure 2). For FE, this trendline resulted in a slope of 0.0026 and a y-intercept of 99.924, while IR resulted in a trendline with a 0.0764 slope and -0.122 y-intercept. The slopes from these trendlines were then used to plot lines that included the current NIOSH criteria at 85 lpm (a minimum FE of 95% and a maximum allowable IR of 35 mmH_2O). Using these new lines with the same slopes, the corresponding NIOSH pass/fail criteria at 30 lpm were determined. These were a maximum allowable IR of 30.83 mmH_2O and a minimum FE of 95.14% at 30 lpm.

Leakage Testing, Pressure Baseline, PM Sensor Verification

The results of leakage testing of the sample chamber can be found in Supplemental Figure 4. These results showed a maxed-out pressure as the chamber was sealed and flow turned off, indicating that there were no leaks in the chamber. The results of the pressure baseline recordings can be found in Supplemental Table II. For each testing day, the Arduino sketch was updated accordingly, as seen in the supplemental material, to reflect the offset of the differential pressure sensor. Lastly, the results for the PM sensor verification can be seen in Supplemental Table III. The PM sensors at worst performed at a 3.32% difference from each other which was within the 5% limit deemed acceptable. This limit was significant as it matched the acceptable 5% of aerosols that are allowed to pass through an N95 FFR according to NIOSH standards.

Steady State Determination

Prior to executing testing, the ATI 100Xs and LREM were run until steady state was reached on all necessary sensors and components. On the ATI 100Xs, steady state for percent penetration measurements was reached after 60 s when testing at lower flow rates such as 10 lpm (Supplemental Figure 5). This lower flow rate was chosen to be consistent with testing across multiple flow rates on the ATI 100Xs. For the LREM, steady state for all measurements was obtained after 100 s at 30 lpm (Supplemental Figure 6).

LREM vs. ATI 100Xs

Table I lists the FE recorded on both the ATI 100Xs and the LREM at 30 lpm while Table II lists the IR. The results of hypothesis testing (whether the differences between the means are statistically significant) as well as the percent difference are also summarized. All the sample groups showed normality via a Kolmogrov-Smirnov test. Outliers were found and removed from the 3M 8210 N95 FFRs, the Lutema M95c children's masks, and the Hanes cotton mask groups tested on the ATI 100Xs based on results of a generalized extreme Studentized deviate test. In terms of pass/fail status for the N95 FFRs, masks tested on both setups pass in accordance with the shifted criteria at 30 lpm.

Table III shows the rank ordered performance of the respirators, masks, and materials for both the LREM and ATI 100Xs. The difference in order from the ATI 100Xs and the LREM was then calculated. For all samples tested, the LREM and ATI 100Xs both show similar trends across performance.

Table I. Summary of Average FE (%) amongst the Tested Respirators, Masks, and Materials on both the ATI 100Xs and LREM (n for ATI 100Xs, LREM)

	ATI 100Xs		LREM		*Statistically*	
Sample (n for ATI 100Xs, LREM)	*Avg. FE*	*Std.*	*Avg. FE*	*Std.*	*Significant?*	*% Difference*
3M 8210 N95 FFRs (n=19,18)	99.800	0.154	99.916	0.071	Yes	0.12%
Shanghai Tenry KN95 Respirators* (n=9,9)	99.525	0.128	99.851	0.075	Yes	0.33%
Lutema M95c Children's Face Masks (n=4,5)	99.987	0.002	99.861	0.090	Yes	0.13%
Halyard H100 Sterilization Wrap (n=7,7)	47.566	2.035	68.275	1.416	Yes	35.75%
GEMS H600 Sterilization Wrap (n=6,6)	19.440	6.022	82.07	4.110	Yes	123.40%
Hanes Reuasble Cotton Masks (n=8,10)	11.048	4.329	25.754	1.390	Yes	79.92%
VPAYI Resuable Cloth Mask with PM2.5 Filter (n=5,5)	24.914	3.296	33.594	1.621	Yes	29.67%
Parquet Polyester Mask (n=6,6)	0.650	0.762	11.078	4.379	Yes	177.83%
Cloth Bandana (n=3,3)	0.000	0.000	0.103	0.580	Yes	200.00%
Neck Gaiter (n=3,3)	0.000	0.000	6.246	1.434	Yes	200.00%
*GB2626-2019 (KN95) Specification						

Table II. Summary of IR (mmH_2O) amongst the Tested Respirators, Masks, and Materials on both the ATI 100Xs and LREM (n for ATI 100Xs, LREM)

	ATI 100Xs		LREM		*Statistically*	
Sample (n for ATI 100Xs, LREM)	*Avg. IR*	*Std.*	*Avg. IR*	*Std.*	*Significant?*	*% Difference*
3M 8210 N95 FFRs (n=19,18)	2.1	0.1	2.2	0.1	Yes	4.09%
Shanghai Tenry KN95 Respirators* (n=9,9)	4.8	0.1	5.7	0.2	Yes	16.97%
Lutema M95c Children's Face Masks (n=4,5)	7.9	1.0	7.0	0.8	No	11.23%
Halyard H100 Sterilization Wrap (n=7,7)	2.8	0.1	2.9	0.1	No	2.52%
GEMS H600 Sterilization Wrap (n=6,6)	8.5	0.2	8.1	0.5	No	3.88%
Hanes Reuasble Cotton Masks (n=8,10)	1.7	0.2	1.8	0.2	No	8.63%
VPA YI Resuable Cloth Mask with PM2.5 Filter (n=5,5)	9.9	0.3	9.0	0.6	Yes	9.35%
Parquet Polyester Mask (n=6,6)	1.3	0.3	1.4	0.2	No	4.76%
Cloth Bandana (n=3,3)	0.1	0.1	0.1	0.0	No	22.22%
Neck Gaiter (n=3,3)	0.4	0.0	0.4	0.1	No	0.84%
*GB2626-2019 (KN95) Specification						

Table III. Rank Order Data of the Respirators, Masks, and Materials on both the ATI 100Xs and LREM for both FE and IR (n for AT I100Xs, LREM)

FE Rank Order			
Sample (n for ATI 100Xs, LREM)	ATI 100Xs	LREM	Difference
Lutema M95c Children's Face Masks (n=4,5)	1	2	1
3M 8210 N95 FFRs (n=19,18)	2	1	1
Shanghai Tenry KN95 Respirators* (n=9,9)	3	3	0
Halyard H100 Sterilization Wrap (n=7,7)	4	5	1
VPA YI Reusable Cloth Mask with PM2.5 Filter (n=5,5)	5	6	1
Medline Super-Heavyweight Sterilization Wrap (n=6,6)	6	4	2
Hanes Reusable Cotton Masks (n=8,10)	7	7	0
Parquet Polyester Mask (n=6,6)	8	8	0
Cloth Bandana (n=3,3)	9	10	1
Neck Gaiter (n=3,3)	9	9	0
IR Rank Order			
Sample (n for ATI 100Xs, LREM)	ATI 100Xs	LREM	Difference
Cloth Bandana (n=3,3)	1	1	0
Neck Gaiter (n=3,3)	2	2	0
Parquet Polyester Mask (n=6,6)	3	3	0
Hanes Reusable Cotton Masks (n=8,10)	4	4	0
3M 8210 N95 FFRs (n=19,18)	5	5	0
Halyard H100 Sterilization Wrap (n=7,7)	6	6	0
Shanghai Tenry KN95 Respirators* (n=9,9)	7	7	0
Lutema M95c Children's Face Masks (n=4,5)	8	8	0
Medline Super-Heavyweight Sterilization Wrap (n=6,6)	9	9	0
VPA YI Reusable Cloth Mask with PM2.5 Filter (n=5,5)	10	10	0
*GB2626-2019 (KN95) Specification			

Venturi Setup

The results of initial testing with the venturi and the LREM setup (Supplemental Figure 7) compared to the ATI 100Xs are summarized in Supplemental Table IV. One outlier was removed from the ATI 100Xs test group. The venturi and LREM setup performed within 2% of the ATI 100Xs for IR and within 1% for FE. All N95 FFRs tested matched pass/fail designations across both testing methods.

DISCUSSION

For this study, the LREM was directly compared to the ATI 100Xs. Comparisons of the ATI 100Xs and LREM's specifications as well as those for the TSI 8130A can be seen in Table IV (TSI Incorporated, 2022) (Air Techniques International, 2022).

Table IV. A Comparison of the TSI 8130A, ATI 100Xs, and the LREM's Specifications

	TSI 8130A	ATI 100Xs	LREM
Cost	> $100,000	> $100,000	< $6,000
NaCl Concentration (g/cm^3)	x	0.04	0.0004
Particle Size (µm)	0.075*	0.075*	~0.075**
Geometric Standard Deviation	≤ 1.86	≤ 1.86	2.00
Aerosol Concentration (µg/L)	12 to 25	10 to 25	< 1
Aerosol Mass Conc. Detection Range (µg/L)	1 to > 200	0.0001 to > 200	0.01 to 1
Aerosol Detection Size Range (µm) (MMAD)	x	x	0.3 to 10
Pressure Range (mmH2O)	0 to 250	0 to 100	± 254
Flow Rate (lpm)	10 to 110	10 to 120	10 to 30
* = count median diameter, ** = geometric mean			

To keep costs low, the LREM makes sacrifices on performance, particularly with regard to flow rate. Airflow for this setup was constrained by the laboratory's vacuum air wall supply and the pressure drop across the flow controller. As a result, further steps were necessary to better understand the effect that flow rate had on FE and IR. It was expected that testing at this reduced flow rate would have an impact and that the samples would not be challenged to the same degree they would be at 85 lpm. Results from Tukey's range test on a set of 3M 8210 N95 FFRs confirmed this as the test values were statistically different at 30 and 85 lpm for FE and IR.

To confirm that the LREM with airflow at 85 lpm would have results matching the ATI 100Xs, particularly with regard to NIOSH pass/fail status for the N95 FFRs, a venturi system was added to the LREM. The LREM and venturi setup performed well at 85 lpm, but the flow rate was inconsistent and less controllable compared to using the flow controller at a lower flow rate. Using a flow controller with the venturi was investigated, but the flow was unable to reach 85 lpm due to the high internal resistance of the flow controller. So, although the flow rate with the venturi was uncontrolled, the results from testing with the N95 FFRs on both the LREM and ATI 100Xs at 85 lpm were similar. The N95 FFRs tested on both setups passed NIOSH standards and there was a small percent difference between the groups. Thus, testing at the lower 30 lpm was deemed appropriate.

The lower 30 lpm flow rate is also physiologically representative for testing when considering that a typical adult male at sea level will have a resting breathing rate of 6 lpm (Pleil, 2021). This breathing rate increases to 16 lpm during normal activity and 40 lpm during moderate exercise (Pleil, 2021). So, although the LREM without the venturi does not operate at 85 lpm, a breathing rate of 30 lpm would still challenge the sample in a more stringent manner compared to 16 lpm, a normal activity breathing rate.

The LREM will provide this flow at a continuous rate as opposed to a normal breathing pattern where the instantaneous flow rate will be higher than the average per minute volume.

Alongside the limitations with flow rate, the LREM also bypasses aerosol neutralization, which is accounted for by the ATI 100Xs and TSI 8130A (Air Techniques International, 2018) (TSI Incorporated, 2022). NIOSH standards require aerosols to be neutralized in order to eliminate the natural attraction between filter materials and aerosols, making it harder for filtration (Schall, 2021). Not accounting for this with the LREM is a potential explanation for the higher FEs seen in Table I compared to the ATI 100Xs values. Fit testing is also a crucial aspect to consider for respirator use on an individual basis, and none of the ATI 100Xs, TSI 8130A, or LREM take this into account and instead assume perfect fits with the hot glue seal. Thus, these results cannot be related to fit testing and further steps will be necessary to determine individual fit and true respirator performance.

Additional steps were necessary to verify the performance of the LREM before comparisons could be made to the ATI 100Xs. Leakage testing was primarily concerned with the bottom half of the sample chamber and the tubing and connections that led to the vacuum wall source. It was expected that while the chamber was blocked and sealed with the aluminum sheet that pressure would remain constant when the suction flow was shut off, indicating that there were no leaks. Results from this testing confirmed that no leaks were present and therefore resistance values were completely attributed to sample performance. The pressure baseline step was performed to calibrate the pressure sensor. With unobstructed flow, the differential pressure sensor should record 0 mmH2O, so the sensor reading was adjusted to reflect that. Lastly, in terms of setting up the LREM, verifying the PM sensors' performance was necessary to confirm that during unobstructed flow the two sensors were reading almost identical particle counts, as close to 0% difference as possible. For this setup, less than a 5% difference was accepted (matching the allowable 5% of aerosols that may penetrate through an N95 FFR). This was confirmed before all tests.

Based on the results seen in Tables I and II, the LREM shows mixed performance. For the respirators and higher performing samples, the LREM performs within 1% of the ATI 100Xs. For the N95 FFRs, the LREM is able to accurately predict NIOSH pass/fail status and match the ATI 100Xs at the lower 30 lpm criterion. The LREM also shows good precision as seen by the small deviations in each sample group. For IR, the N95 FFRs tested also pass on both setups, and once more, the LREM shows strong precision. The LREM also shows better overall performance for IR as opposed to FE.

The LREM was also able to determine rank order of sample performance for both FE and IR as seen in Table III. All but one mask for FE is within one spot of the rankings, and for IR, the samples are ranked the same on both test setups. These results help to characterize the overall performance of the LREM and its ability to distinguish between well performing respiratory-protective devices and poorly performing ones. This will be crucial in the LREM's purpose of helping to advance and develop innovative respirator and mask designs.

CONCLUSIONS

Overall, the LREM was constructed for approximately 6% the cost of the ATI 100Xs and TSI 8130A and offers promise as an accessible and low-cost testing option. While the LREM is limited in its performance when compared to current evaluation devices, it can provide useful data regarding the general performance of a respirator, mask, or material. We believe the LREM could serve as a first pass testing method to provide ongoing test performance data during respirator development prior to official testing using an ATI 100Xs or TSI 8130A. The LREM would be particularly useful in the development of innovative respirators and masks or in testing alternative materials for each and can help guide manufacturers or developers with design modifications. This itself can be more beneficial than repeatedly

paying for and sending away masks to a facility that offers testing on a current evaluation device. Future work will address the current limitations of the LREM and enhance its overall performance, particularly with regard to improving FE results. Additionally, other flow controllers will be investigated to see which have lower internal resistances and can be incorporated with the venturi to match the 85 lpm flow. Further tailoring the LREM such that it can provide more physiologically relevant data, such as by mimicking breathing rates and patterns, is also of interest.

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REFERENCES

3M Company. (n.d.) 3M Infection Prevention, N95 Particulate Respirators, 1860/1860S and 1870, Frequently Asked Questions. 3M Company, St. Paul, MN. https://multimedia.3m.com/mws/media/323208O/n95-particulate-respirators-1860-1860s-1870-faqs.pdf

Air Techniques International. (2022) 100x Automated Filter Tester. Air Techniques International, Owings Mills, MD. https://www.atitest.com/products/100x-automated-filter-tester/.

Air Techniques International. (2018) Theory of Operation for the 100Xs. Air Techniques International, Owings Mills, MD. https://ati.zendesk.com/hc/en-us/articles/360002933932-Theory-of-Operation-for-the-100Xs.

All Sensors. (n.d.) DLLR – High Accuracy Pressure Sensors Series. All Sensors Corporation, Morgan Hill, CA. No. DS-0358 Rev A. https://media.digikey.com/pdf/Data%20Sheets/Amphenol%20All%20Sensors%20Corp/DS-0358%20Rev%20A%20DLLR.PDF

Centers for Disease Control and Prevention. (2021) How coronavirus spreads. Centers for Disease Control and Prevention, Atlanta, GA. https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.

Centers for Disease Control and Prevention. (2021) Respirator FAQs. Centers for Disease Control and Prevention, Atlanta, GA. https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsource3basic.html.

Centers for Disease Control and Prevention. (2021) Science Brief: Community Use of Masks to Control the Spread of SARS-CoV-2. Centers for Disease Control and Prevention, Atlanta, GA. https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/masking-science-sars-cov2.html.

Centers for Disease Control and Prevention. (2022) Types of Masks and Respirators. Centers for Disease Control and Prevention, Atlanta, GA. https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html

Code of Federal Regulations. (2021) *Approval of Respiratory Protective Devices*. U.S. Government

Printing Office, Office of the Federal Register, Washington, DC. Title 42, CFR, Part 84. https://www.ecfr.gov/current/title-42/chapter-I/subchapter-G/part-84

Collins AP, Service BC, Gupta S, Mubarak N, Zeini IM, Oshbahr DC, et al. (2021) N95 respirator and surgical mask effectiveness against respiratory viral illnesses in the healthcare setting: A systematic review and meta-analysis. *Journal of the American College of Emergency Physicians Open.* doi.org/10.1002/emp2.12582

Finlay WH and Darquenne C. (2020) Particle Size Distributions. Journal of Aerosol Medicine and Pulmonary Drug Delivery. doi.org/10.1089/jamp.2020.29028.whf

Landry SA, Subedi D, Barr JJ, MacDonald MI, Dix S, Kutey DM, et al. (2022) Fit-tested N95 masks combined with portable high-efficiency particulate air filtration can protect against high aerosolized viral loads over prolonged periods at close range. *The Journal of Infectious Diseases.* doi.org/10.1093/infdis/jiac195

LaRue RJ, Morkus P, Laengert S, Rassenberg S, Halali MA, Colenbrander JW, et al. (2021) Navigating performance standards for face mask materials: A custom-built apparatus for measuring particle filtration efficiency. *Global Challenges.* doi.org/10.1002/gch2.202100052

Lyu W and Wehby GL. (2020) Community use of face masks and COVID-19: Evidence from a natural experiment of state mandates in the U.S. *Health Affairs.* doi.org/10.1377/hlthaff.2020.00818

National Institute for Occupational Safety and Health. (2019) *Determination of Exhalation Resistance Test, Air-Purifying Respirators Standard Testing Procedure.* National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, Pittsburgh, PA. No. TEB-APR-STP-0003-508. https://www.cdc.gov/niosh/npptl/stps/pdfs/TEB-APR-STP-0003-508.pdf

National Institute for Occupational Safety and Health. (2019) *Determination of Inhalation Resistance Test, Air-Purifying Respirators Standard Testing Procedure.* National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, Pittsburgh, PA. No. TEB-APR-STP-0007-508. https://www.cdc.gov/niosh/npptl/stps/pdfs/TEB-APR-STP-0007-508.pdf

National Institute for Occupational Safety and Health. (2019) *Determination of Particulate Filter Efficiency Level for N95 Series Filters Against Solid Particulates for Non-Powered, Air-Purifying Respirators Standard Testing Procedure.* National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, Pittsburgh, PA. No. TEB-APR-STP-0059-508. https://www.cdc.gov/niosh/npptl/stps/pdfs/TEB-APR-STP-0059-508.pdf

Pleil JD, Ariel Geer Wallace M, Davis MD, Matty CM. (2021) The physics of human breathing: Flow, timing, volume, and pressure parameters for normal, on-demand, and bentilator respiration. *Journal of Breath Research.* doi.org/10.1088/1752-7163/ac2589

Schall J, Coffey C. (2021) Understanding filtration efficiency testing and fit testing in filtering facepiece respirators (FFR). National Institute for Occupational Safety and Health, Pittsburgh, PA. No. 2021-123. doi.org/10.26616/NIOSHPUB2021123revised112021

Sensirion. (2020) Datasheet SPS30 Particulate Matter Sensor for Air Quality Monitoring and Control. Sensirion, Stäfa, Switzerland. https://sensirion.com/media/documents/8600FF88/616542B5/Sensirion_PM_Sensors_Datasheet_SPS30.pdf

Standardization Administration of China. (2019) *Respiratory Protection – Non-powered air-purifying*

particulate respirator. Standardization Administration of China, Beijing, China. No. GB2626-2019.

TSI Incorporated. (2012) Aerosol Statistics, Lognormal Distributions and dN/dlogDp. TSI Incorporated, Shoreview, MN. https://tsi.com/getmedia/1621329b-f410-4dce-992b-e21e1584481a/PR-001-RevA_Aerosol-Statistics-AppNote?ext=.pdf

TSI Incorporated. (2022) Certitest Automated Filter Tester Model 8130A. TSI Incorporated, Shoreview, MN. https://tsi.com/getmedia/061e0676-ae77-43c5-baf3-f8bd1fd2fb93/Filter%20Tester%208130A_US_5001770_RevC_Web?ext=.pdf

TSI Incorporated. (2013) Constant Output Atomizer Model 3076 Operation and Service Manual. TSI Incorporated, Shoreview, MN.

U.S. Food and Drug Administration. (2021) N95 Respirators, Surgical Masks, Face Masks, and Barrier Face Coverings. U.S. Food and Drug Administration, Silver Spring, MD. https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-surgical-masks-face-masks-and-barrier-face-coverings.

Van Dyke ME, Rogers TM, Pevzner E, Satterwhite CL, Shah HB, Beckman WJ, et al. (2020) Trends in County-Level COVID-19 Incidence in Counties With and Without a Mask Mandate – Kansas, June 1 – August 23, 2020. *Morbidity and Mortality Weekly Report.* doi.org/10.15585/mmwr.mm6947e2

World Health Organization. (2021) Coronavirus disease (COVID-19): How is it transmitted?. World Health Organization, Geneva, Switzerland. https://www.who.int/news-room/questions-and-answers/item/coronavirus-disease-covid-19-how-is-it-transmitted.

World Health Organization (WHO). (2020) WHO Director-General's opening remarks at the media briefing on COVID-19 – March 2020. World Health Organization, Geneva, Switzerland. https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020.