

A Modified Method for Measuring Pressure Drop in Non-medical Face Masks with Automated Data Acquisition and Analysis

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ABSTRACT

Background: Non-medical face masks, such as face coverings donned by the general population play an important role in reducing transmission of respiratory pathogens. Pressure drop or breathability of such masks is an important attribute especially with the advent of new standards such as ASTM F3502-21 that have specified pressure drop limits for general use of face coverings. Although several standards are available that discuss pressure drop measurement techniques, the methodologies reported are typically complex or are part of more sophisticated and expensive instruments. Thus, the applicability of such methods is often limited to medical device manufacturers.

Objective and Methods: This manuscript adapts from the pressure drop measurements proposed in British Standard EN 14683:2019 and describes a methodology to create a simple 3D printed model of a pressure rig for measuring the breathing resistance across non-medical face masks. The method also enables real time pressure drop data acquisition and analysis of multiple samples or batches using Python and MATLAB scripts.

Results: We performed a validation study by comparing the pressure drop obtained for one brand of respirators with our set up and compared it with data obtained by traditional means by CDC. An unpaired two-tailed student t-test ($n=3$) between the two means implied no statistically significant difference.

Conclusion: The method we have developed can be easily implemented at community levels for characterizing the breathability of non-medical grade face masks.

Keywords: pressure drop, breathing resistance, face coverings, COVID-19, masks, facemasks

INTRODUCTION

Face coverings made for general use (Center for Disease Control, 2021) and respirators for healthcare workers (Bartoszek et al., 2020; Radonovich et al., 2019) are playing an important role in slowing the spread of COVID-19. There are three key attributes for such medical and non-medical masks – filtration, pressure drop and fit. While the importance of filtration and fit is readily apparent, the pressure drop (the breathing resistance at a specified flow rate) across a mask is also a vital factor to consider. The physiological effects of breathing resistance are complex. Temperature and humidity (Kim et al., 2016; Roberge et al., 2012) can increase physiological stress on the wearer. These considerations involve highly complex interactions and are highly dependent upon the wearer. In addition, excessive breathing resistance can lead to discomfort and amplify the effect of leakage. Although the physiological process of breathing resistance is complex, certain simplifying assumptions can be made. For example, although breathing flow rate varies sinusoidally, the materials and construction of these devices almost universally

involve a linear relationship between flow rate and pressure drop over the range of human breathing (Shykoff et al., 2010). Therefore, measuring pressure drop at a single flow rate is sufficient to represent the breathability in most cases (Rottach et al., 2020). Assuming heterogeneity of the material properties across the entire non-medical mask, the second simplification possible is the consideration of a coupon of material rather than an entire mask.

While several standardized methodologies are available for filtration and fit (National Institute for Occupational Safety and Health, 2019b; Coffey et al., 2010), the techniques available for measuring pressure drop can be chosen from approaches requiring specialized full-size head forms (British Standards Institution, 2009; National Institute for Occupational Safety and Health, 2019a) or specialized metallic housings (British Standards Institution, 2019), using state of the art aerosol instruments that are capable of measuring pressure drop (Greenawald et al., 2020), or alternately are silent on how to measure the pressure drop across barrier materials (ASTM, 2021). The literature lacks any specific methodology that can be easily implemented for non-medical masks without sophisticated instruments. During the COVID-19 pandemic, academicians or manufacturers have made their own pressure measurement rigs and have at times reported incorrect pressure drop values (Konda et al., 2020) as has been critiqued elsewhere (Carr et al., 2020).

We address the lack of simple tools specifically dedicated for pressure drop measurements across coupons of face coverings by adapting the BS EN 14683:2019 and by modifying the breathing resistance protocol of this standard (as found in Annex C therein) to develop an easy to fabricate, and easy to use pressure drop rig. The modified method we propose here is different from the original approach in several ways:

- Used easily accessible 3D printers to print parts for building the rig.
- Used two pressure transducers that cover the pressure drop range likely to be encountered in a variety of household materials.
- Automated the data acquisition.
- Automated the data analysis.

All files necessary, including software code, are made available in the supporting information so manufacturers, hospitals, or other community stakeholders can use them directly for building their own rig.

MATERIALS AND METHODS

Design of the pressure drop rig

We adapt from *British Standard EN 14683:2019 – Medical face masks – Requirements and test methods*, Annex C, which, to our knowledge, provides the most thorough description on how to build a pressure rig. Briefly, the rig in this standard involves two sample holders sandwiched together with the testing sample in between, and a 3 mm spacing maintained with a metallic ring between the two holders. The inner diameter of the metallic ring is $25\text{ mm} \pm 1\text{ mm}$. The sandwiched sample holders are secured using a screw or a lever and a final adjustment between the fixture and the levers. Flow meters are present on the inlet and outlet of the fixture and flow is controlled by a valve that is hooked to a vacuum source. A differential pressure transducer or differential manometer is acceptable per the standard.

For our setup we decided to 3D print the sample holder for ease of manufacturing. Figure 1A shows an exploded view of the various parts of the sample holder including the pressure measurement ports, and 1B shows the rig in its final constructed form. The corresponding computer aided design (CAD) file is provided in the attached document. We kept the $25\text{ mm} \pm 1\text{ mm}$ dimension for the opening. The 3mm spacing provided by metallic rings from the original standard were replaced with a 3 mm ring combined into the 3D printed upper and lower fixtures to become a raised lip. This lip and was smoothed after printing. Two 3/32" silicone gaskets are cut to go around the raised 3 mm lip and fit within the upper and lower fixtures and between the sample under test (See Figure 1A). The 3D printed sample holder (upper and lower fixtures) has holes for the flow and pressure port fittings to be secured with RTV. The

flow ports were 3/8" barb fitting while the pressure measurement ports are standard luer lock fittings that connect to the pressure transducer. A TSI Flow Meter (4143, TSI Inc, Shoreview, MN) was used for the flow meter upstream of the fixture. This flow meter has an accuracy of 2% of reading or .005 Std L/min, whichever is greater. In lieu of a flow meter and valve downstream we utilized a vacuum mass flow controller (MCR-50SLPM/D/5M, Alicat Scientific Inc., Tucson, AZ) to control the flow to a specific set point in SLPM. This flow controller has an accuracy of 0.8% of reading plus 0.2% of full scale with a repeatability of 0.2% of the full scale. A 0.2 μ m filter is required before the mass flow controller to prevent debris from getting to it (Millipore Sigma, Burlington, MA). Figure 1C provides a picture of the set up and the directions are that of the incoming and outgoing air. The schematic of the flow loop along with the pressure drop rig is shown in Figure 2.

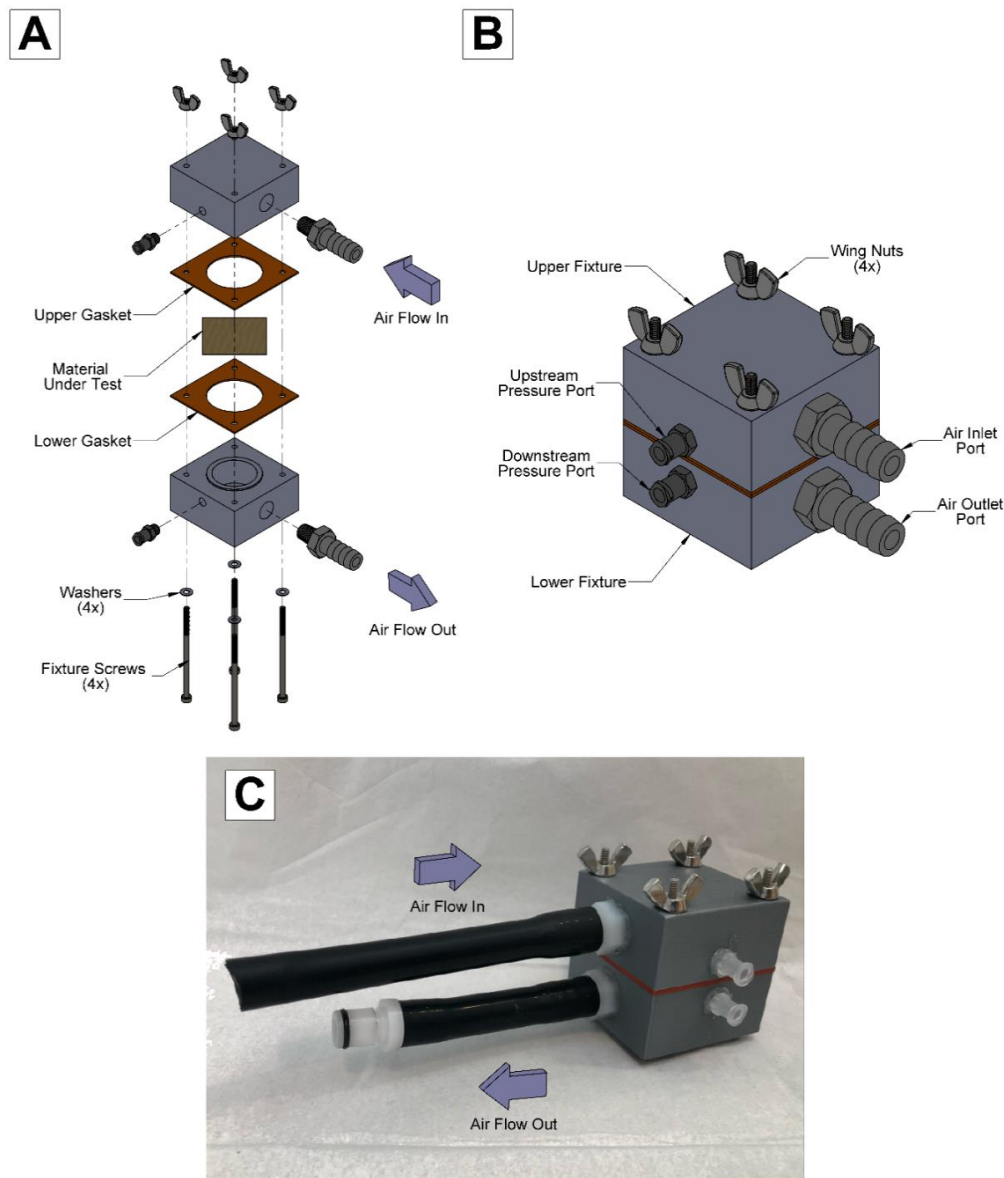


Figure 1: (A) Exploded SolidWorks CAD design of the modified pressure drop rig. (B) CAD design of the pressure drop rig in its assembled form. (C) 3D printed pressure drop rig with direction of flow inlet and outlet. The two Luer ports to the right go to the pressure transducer.

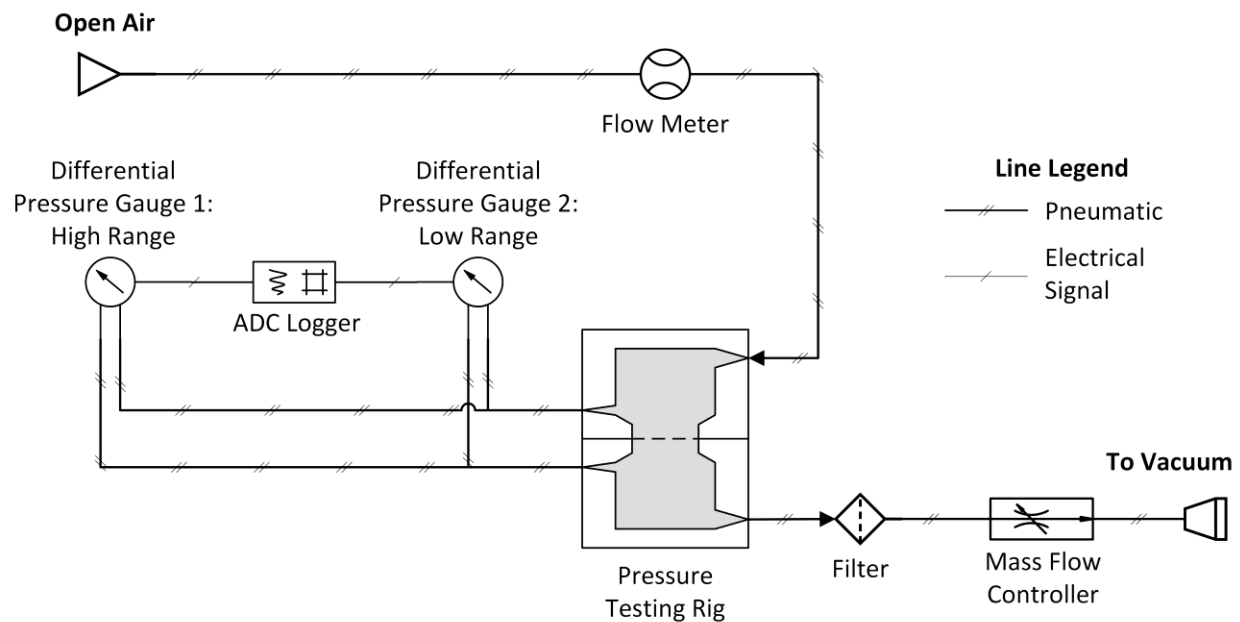


Figure 2. Schematic of the modified pressure drop rig with pressure transducer used in this article.

Components of the experimental set-up

The pressure drop rig can perform a real time check of the flow rate through the inlet (by using a flowmeter) and compare against the outlet flow rate (controlled using a mass flow controller) and thus enables real time verification that the leak in the test rig is minimal. Details of flow loop components are in Table I below.

We fabricated the 3D printed components on a PRUSA i3 MK3S (Prusa Research, Prague, Czechia) using MatterHackers (MatterHackers, Lake Forest, CA) silver MH Build series polylactic acid (PLA) filament (1.75 mm nominal diameter). The STL files were sliced in PrusaSlicer (Prusa Research, Prague, Czechia) and printed with a 0.25 mm brass nozzle, a layer height of 0.2 mm, a nozzle velocity of 25-60 mm/s, and an extrusion temperature of 210-215 °C.

The PX165 low range differential pressure transducers have a range of 0.25 to 2 inH₂O, has an accuracy of $\pm 1\%$, a stability of $\leq \pm 0.50\%$ span/year, and a proof pressure of 7.25 psi. The ADS1115 is an analog to digital convertor (ADC) that has a 16-bit output resolution, up to 860 samples per second sampling rate, and an offset error and gain error of ± 3 LSB and 0.01% respectively.

The pressure drop set up has a real time verification of flow and leakage built in to the set up that enables the measurement of the volumetric flow rate before and after the coupon, and thus ensures that there is no leak in the test rig.

Table I. Components of the Pressure Drop Measurement Rig Including All Parts

Name	Manufacturer	Model	Description
Differential Pressure Gauge 1	OMEGA Engineering	PX165-002U	2 inH ₂ O Pressure Transducer
ADC Logger	Adafruit, & Raspberry Pi Foundation	ADS1115, & 4B	ADC Logger made from a 16 Bit ADC, and a Raspberry Pi 4B
Flow Meter	TSI Inc.	4143	General Purpose Flow Meter, 3/8", 20 LPM, Air, O ₂ , N ₂
Pressure Drop Rig	U.S. FDA	AM_PDdrop_Fixture_v1	3D Printed Pressure Drop Test Fixture, 25mm Sample Opening
Filter	Millipore Sigma	Opticap XL 4	0.2um Filter for the protection of the MFC
Mass Flow Controller	Alicat Scientific Inc.	MCR-50SLPM-D/5M	Vacuum Mass Flow Controller, 5IN DS, Air, 0 - 50 LPM
Differential Pressure Gauge 2	OMEGA Engineering	PX165-0.25U	0.25 inH ₂ O Pressure Transducer

Automated Pressure Transducer Data Acquisition using Python

Unlike the BS EN 14683 standard, which proposes use of manometers, we used highly accurate sensitive pressure transducers that allow real time data acquisition that can subsequently be averaged over time. This pressure measurement system consisted of a Raspberry Pi 4 Model B (Raspberry Pi Foundation, Cambridge, UK), an ADS1115 4 channel 16-bit ADC (Adafruit, New York, NY), and two low-range differential pressure transducers with upper ranges to 2.0 inH₂O (498 Pa) (PX165-002U, OMEGA, Norwalk, CT) and 0.25 inH₂O (62 Pa) (PX165-0.25U, OMEGA, Norwalk, CT).

The ADS1115 is connected to the Raspberry Pi through I2C communication while the pressure transducer outputs were connected to the ADS1115 and powered by the Raspberry Pi. A Python (Python Software Foundation, Wilmington, DE) script, "presslog.py", was used to record the pressures from the fabric testing apparatus with the ADC in single-ended mode. The frequency of data collection is 10 Hz. The voltage to pressure sensor conversions were done using linear multipliers and offsets (see supporting information). For one transducer the maximum pressure drop limit is $4 \times 1.59 = 6.36$ mmH₂O while for the transducer with the larger range the limit is $4 \times 12.7 = 50.8$ mmH₂O. The script used for data acquisition is provided below. The script would enable logging of the data in "outputfile.txt" file at a frequency of 10 Hz. For stopping the data acquisition, the user can hit "Enter".

A user does not need to know the details behind the transducer and the script to operate the pressure rig. However, some familiarity with the script and the hardware would be desirable if the user would prefer modifications to the data acquisition. For such advanced users, details are provided below.

The ADS1115 analog-to-digital converter (ADC) module connects to the Raspberry Pi through the Pi's General Purpose Input/Output (GPIO) pins. This connection uses the Pi's I2C serial communication functionality through pins 2 and 3. While the ADS1115 is powered from the Pi's 3.3-volt source, the currently chosen pressure transducer is powered from the 5-volt source. The ADS1115 ADC module will operate all four channels in single-ended mode, meaning the transducer signal grounds will be connected to the system ground. Table II shows the pin connections for the system.

Table II. Pin Connections for the Systems Primary Components

Raspberry Pi	ADS1115	PX165-xxxx	Notes
3.3 V power	Vdd		Power source for the ADC
Ground	GND	COM	Common ground
GPIO 2 (SDA)	SDA		I2C Data communication
GPIO 3 (SCL)	SCL		I2C Clock communication
5V power		V+	Power source for the transducer
	A<chn>	OUT	Ratiometric voltage signal

The Python script uses Adafruit's CircuitPython library to interface with the ADS1115. This library makes it easier to communicate with the ADS1115 through the Pi's I2C interface. Instruction for installing CircuitPython through the Pi's terminal can be found here: <https://learn.adafruit.com/circuitpython-on-raspberrypi-linux/installing-circuitpython-on-raspberrypi-pi>.

Before running the Python pressure logging script, it is essential to know the transducers voltage-to-pressure conversion settings. This is needed because the transducers voltage output range is not 1:1 with the ratiometric pressures. Generally, two settings are needed to convert a ratiometric voltage to a pressure. One is the voltage-to-pressure multiplication conversion (multi) in mmH₂O/V and the other is the pressure offset (offset) in mmH₂O from 0 volts. Table III shows the pressure multiplication conversion and pressure offset for converting voltage measured from pressure transducer into mmH₂O.

Table III. ADC Conversion Constants Used to Obtain Pressure Readings in mmH₂O

	Voltage conversion, multi<chn> (mmH ₂ O/V)	Pressure Offset, offset<chn> (mmH ₂ O)
ADC Channel 0 (PX165-0.25U)	1.588	-0.794
ADC Channel 1 (PX165-002U)	12.700	-6.35

The python script accepts terminal arguments that are detailed in Table IV. In a Linux or other compatible command line console, running the Python script starts the program interface.

Table IV. Python Script "presslog.py" Command Line Arguments and Descriptions

Script Argument	Example Argument	Argument Description
-o <filename>	-o testfile.txt	Defines output filename
-f <recording freq>	-f 10.0	Defines ADC recording frequency
--multi<chn>=<conv multiplier>	--multi0=1.588	Defines the unit conversion multiplier in units/V
--offset<chn>=<pressure offset>	--offset0=0.794	Defines the pressure offset in units
--units<chn>=<pressure units>	--units0=mmH ₂ O	Defines the pressure units

Using the sensor conversion values and arguments above, an example of how to run "presslog.py" on a Linux system is shown below:

```
pi@raspberrypi:~ $ python3 presslog.py -o outputfile.txt -f 10 --multi0=1.588 --offset0=-0.794 -units0=mmH2O
```

This would read channel 0 on the ADC at a frequency of 10 Hz, and set the multiplication and offset factor to 1.588, -0.794, and mmH₂O respectively. This would also tell the program that the logging filename is "outputfile.txt".

Figure 3 shows an image of the presslog.py interface where the user can log the pressure transducer data. To start recording the voltage and pressure data, one needs to press the space bar. Once finished recording, hit the 'c' key. This process can repeat as many times as the user wants for the current root filename. The user should notice that every time data logging is initiated, a new date and timestamp is appended to the data file. To exit the program, one needs to simply hit the 'Enter' key. An example text output for presslog.py is shown in Figure 4.

```

@RPI4PC: ~/Share/Programming/Python/Pressure Logging/Release
File Edit Tabs Help
Running: presslog.py Version 20210419 By Daniel Porter
Date Time is : 2021_05_04 13:12:28
Filename = MyPressureData.txt, ADS Gain = 0.667, Samp Freq = 10.0 hz, Samp dt = 0.1000 s

Chan | QOI-Multi | QOI-Offset
A0 | 1.58800 | -0.79400
A1 | 12.70000 | -6.35000
A2 | 1.00000 | 0.00000
A3 | 1.00000 | 0.00000

Status = Waiting Time(s) = 6.000 Sample # = 59

Chan | Voltage | Volt-Avg | Volt-Rng | QOI | QOI-Avg | QOI-Rng | Units
A0 | 1.59905 | 1.59971 | 0.00206 | 1.74529 | 2.54033 | 0.00328 | mmH2O
A1 | 1.57280 | 1.57287 | 0.00131 | 13.62453 | 19.97543 | 0.01667 | mmH2O
A2 | 3.16566 | 3.16615 | 0.00338 | 3.16566 | 3.16615 | 0.00338 | Volts
A3 | 0.59608 | 0.59575 | 0.00281 | 0.59608 | 0.59575 | 0.00281 | Volts

<0-3>zero QOI <space>Rec <c>Stop Rec <enter>Quit
Notes:

```

Figure 3. User interface for "presslog.py".

	A	B	C	D	E	F	G	H	I	J	K
1	Running: presslog.py Version 20210419 By Daniel Porter										
2	Date Time is : 2021_05_04 13:12:59										
3											
4	Filename = MyPressureData.txt, ADS Gain = 0.667, Samp Freq = 10.0 hz, Samp dt = 0.1000 s										
5											
6	Chan QOI-Multi QOI-Offset										
7	A0	1.58800	-0.79400								
8	A1	12.70000	-6.35000								
9	A2	1.00000	0.00000								
10	A3	1.00000	0.00000								
11											
12	Sample#	time(s)	V0	V1	V2	V3	QOI0(mmH2O)	QOI1(mmH2O)	QOI2(Volts)	QOI3(Volts)	
13	372	37.221	1.592	1.565	3.134	0.597	1.734	13.522	3.134	0.597	
14	373	37.321	1.591	1.565	3.133	0.596	1.733	13.52	3.133	0.596	
15	374	37.421	1.592	1.565	3.142	0.596	1.734	13.52	3.142	0.596	
16	375	37.521	1.59	1.565	3.133	0.598	1.731	13.52	3.133	0.598	
17	376	37.621	1.591	1.565	3.132	0.596	1.732	13.522	3.132	0.596	
18	377	37.721	1.589	1.564	3.133	0.597	1.73	13.515	3.133	0.597	
19	378	37.821	1.589	1.564	3.133	0.596	1.73	13.517	3.133	0.596	
20	379	37.921	1.589	1.564	3.135	0.596	1.73	13.517	3.135	0.596	
21	380	38.021	1.592	1.565	3.136	0.596	1.734	13.525	3.136	0.596	
22	381	38.121	1.591	1.564	3.133	0.598	1.733	13.517	3.133	0.598	
23	382	38.221	1.593	1.564	3.133	0.596	1.735	13.517	3.133	0.596	
24	383	38.321	1.59	1.565	3.132	0.596	1.731	13.52	3.132	0.596	
25	384	38.421	1.59	1.564	3.135	0.596	1.731	13.517	3.135	0.596	
26	385	38.521	1.591	1.565	3.134	0.596	1.733	13.522	3.134	0.596	
MyPressureData_2021_05_04_13-12											

Figure 4. A screenshot of the data output for example pressure logging session accessed through Microsoft EXCEL® 365.

Automated Data Analysis Using MATLAB

The pressure logging data generated by the Python script is then placed in the same folder as the MATLAB (MathWorks Inc, Natick, MA) instance processing code and ran. The code has the capability to sense if the pressure drop exceeded the limit of the pressure transducers. For low pressure measurements (< 6 mmH₂O) the code averages the pressure drop data from the more sensitive transducer, and for higher pressure measurements it averages data from the second transducer with the wider range. The algorithm used by the MATLAB script is shown in Figure 5 for the benefit of advanced users interested in modifying the code for their specific needs. The code itself is provided in the supporting information. The code is also capable of running multiple output files simultaneously to provide an average across multiple samples. The user can directly use the code provided for analyzing the acquired pressure drop data.

Step by Step Process of Measuring Pressure Drop

Step 1: With no material in the pressure rig fixture, initiate logging of pressure drop as measured by the pressure transducer and turn on the flow meter. The flow meter should read 0.00 L/minute.

Step 2: After waiting > 1 minute, and while continuing to log the pressure drop, turn on the mass flow controller which is preset at the desired volumetric flow rate. If comparing to CDC tested respirators, the flow rate should be set to 2.2 LPM, referred to as Q_{SP} in Table V. The pressure logging can be stopped after a few minutes. The total amount of time for which the logging should be monitored should be greater than the time it takes for the flow controller reading to stabilize to the set point within the flow accuracy tolerance of the flow controller. The pressure drop data is recorded in a tab delimited text file.

Step 3: While post-processing this data it should be ensured that the time-averaged pressure drop is < 0.01 mmH₂O after the flow controller reading stabilizes. This confirms that the pressure rig itself does not contribute to the pressure drop. Further details about post-processing of the data is discussed in Step 10 below.

Step 4: To determine the offset between the flow meter and the mass flow controller and to ensure leaks in the flow loop are minimal, the displayed values in the mass flow controller, and the corresponding value in the flow meter are manually noted and difference between the flow rates should be recorded. This baseline flow-rate offset should be no more than 2%. If it is more than 2%, check for possible leaks in the setup such as gaps in fittings. If necessary, reduce the roughness of the contact points (3mm ring) between the two halves of the rig.

Step 5: Data logging is stopped, and the mass flow controller is turned off. The pressure rig is prepared by placing the fabric inside the rig via removing the wing nuts and the top half of the rig.

Step 6: The single layered or multilayered fabric coupon is gently placed with no tension on the bottom half of the rig. The top half is then applied on top of the bottom half of the rig with the sample and then the rig is tightened. Tightening should be performed carefully and done until all four wing nuts are finger tight. The tightening of the wingnuts should be performed in a crisscross pattern.

Step 7: Pressure Logging is enabled with the pressure transducer, then the flow meter is turned on, followed by the mass flow controller. Allow the volumetric flow rate reading to stabilize. After that, the flow controller and flow meter values are noted, and their difference is recorded.

Step 8: If the difference in this value plus the offset calculated earlier is $> 5\%$ for any coupon, then the tightening of the wing nuts needs to be increased as such high values imply leakage inside the set-up. If the increase in tightening leads to a sudden drop of pressure this is because the strain from the tightening may have resulted in the rupture of the fabric. The actual flow leakage rate can be determined by subtracting averaged ($n=3$) baseline offset in step 4 from flow rate difference measured in step 7 and can vary with different materials. If tightening is needed, go back and redo steps 7 and 8.

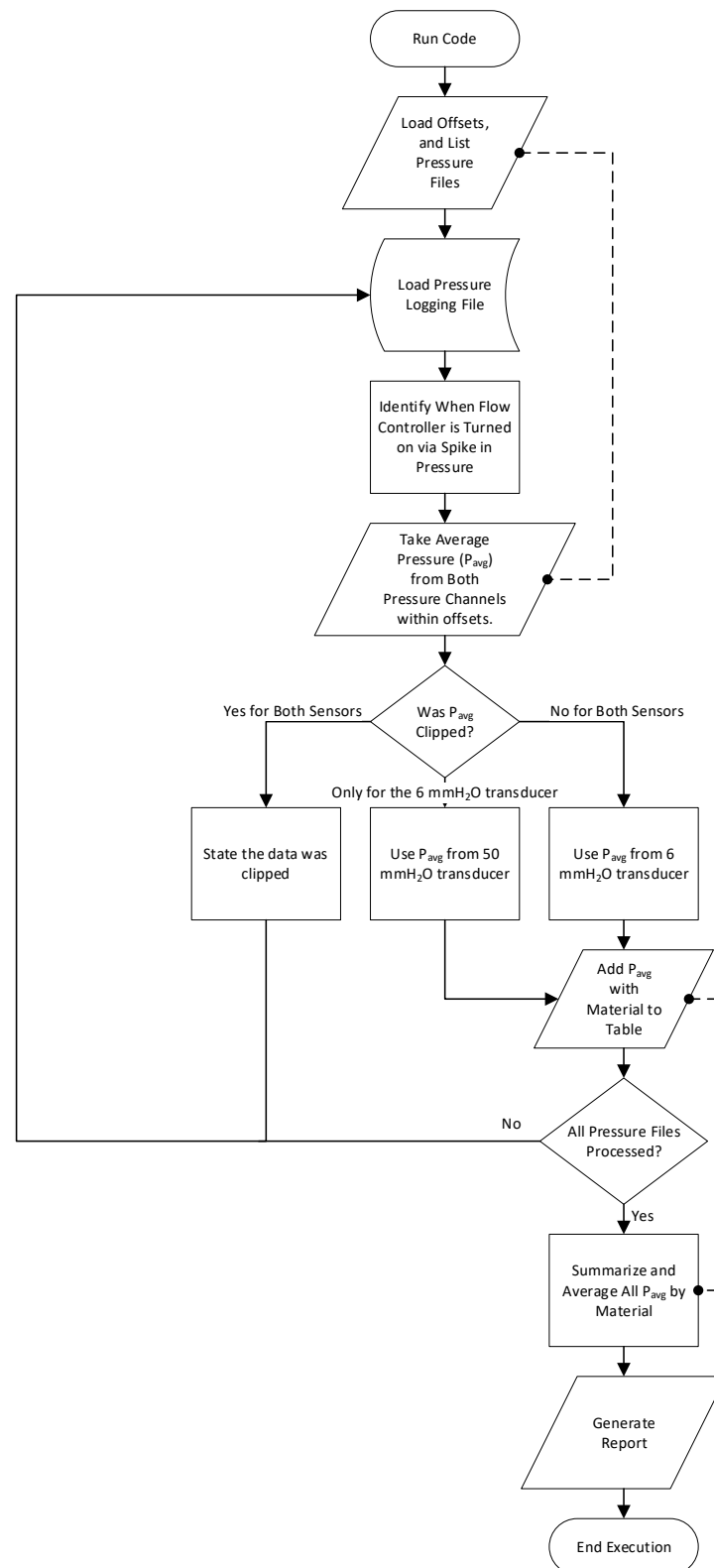


Figure 5. MATLAB algorithm used for automated determination of pressure drop.

Table V. List of Calculations Needed in Procedure

<i>Validation Calculations</i>	<i>Calculation Description</i>	<i>Calculation Found in Step #</i>
$ Q_{FM} - Q_{MFC} = Q_{OS} \leq Q_{SP} \times 0.02$	Flow Meter (Q_{FM}) and Mass Flow Controller (Q_{MFC}) Offset (Q_{OS})	4
$ Q_{FM} - Q_{MFC} + Q_{OS} \leq Q_{SP} \times 0.05$	Flow Meter and Mass Flow Controller Pressure Reading	7 & 8

Step 9: After at least one minute of a steady pressure reading, the mass flow controller and flow meter are turned off, and the experiment is stopped.

Step 10: The text file is then exported to the folder that has the MATLAB script, and the script is then run. Depending on parameters chosen, the script can output reports and plots. Figure 6 provides an example plot for a respirator filter sample. P1 indicates the pressure drop registered by the transducer with the larger pressure drop range. Since the pressure drop of this filter sample exceeded that of the transducer with the lower range of 6.36 mmH₂O, the script did not plot that data. Note that the time-averaging is performed after the pressure drop has sharply risen. This instantaneous pressure drop rise is caused when the mass flow controller is started. The script can then also average the pressure drop across multiple samples/coupons if the acquired data are stored in the same folder.

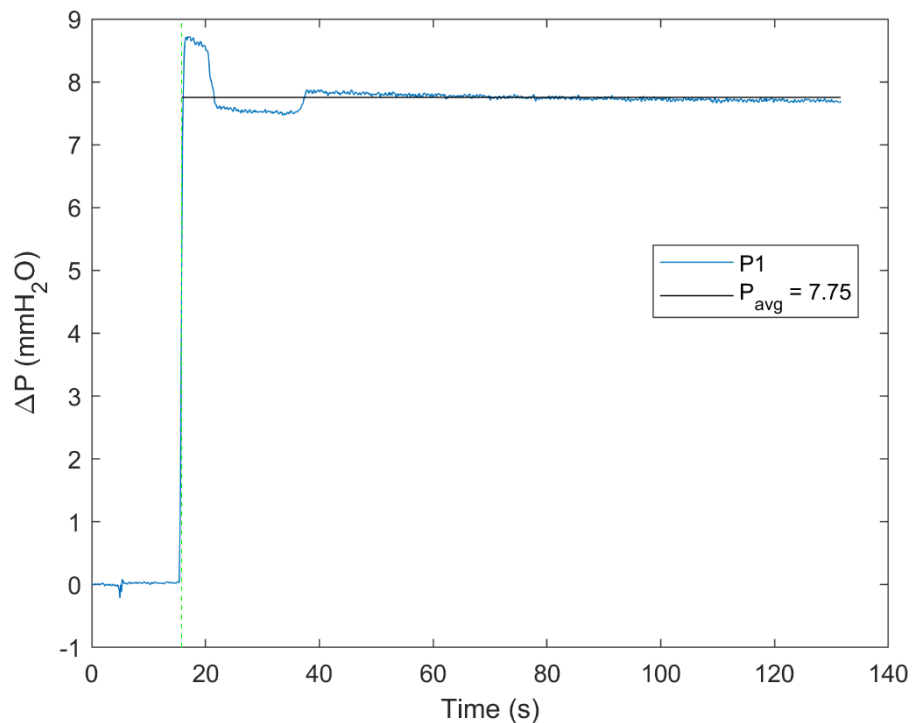


Figure 6. A plot of the pressure log file of a respirator 3M 1860 is shown as one of the possible outputs of the MATLAB code. Although the pressure rig is not intended for measuring pressure drop in respirators this example is provided as part of the data that was used to generate Figure 7.

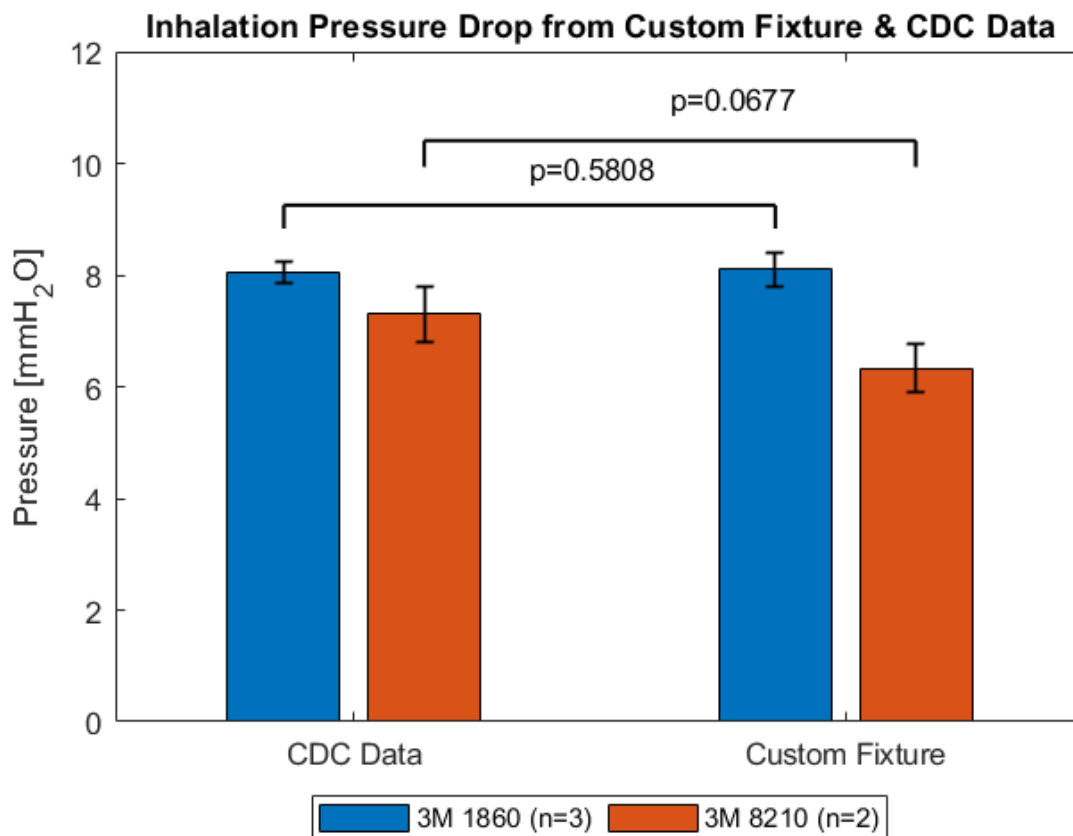


Figure 7. Comparison of data measured by CDC using an independent and commercially available filter tester for a stockpiled 3M 1860 model and a 3M 8210, and data obtained using our modified BS EN 14683 protocol. 8210+ CDC Data from Quinn et al. (2021).

RESULTS: METHOD VALIDATION

Because of lack of any standardized fabric material for which the pressure drop is well known, we used respirator coupons from the 3M 1860 and the 3M 8210. We compared our pressure drop data with data obtained by the CDC (Rottach et al., 2020) for one commonly used respirator model. Since pressure drop is strongly dependent on the flow rate, we needed to ensure that the velocity through our respirator coupons were the same as the velocity used by the CDC. However, the CDC uses flow rate of 85 L/minute for testing and uses the entire respirator. To match our velocity with CDC's, we had to determine the equivalent flow rate for our pressure rig. For that we had to first measure the surface area of the respirator we chose for validation, model 1860 (3M, Minneapolis, MN). The area of the mask was measured by first cutting the mask so it can lay flat. Then it was pressed and flattened with a plexiglass plate. A photo was then taken of the flat area and this area was then measured in ImageJ (Schneider et al., 2012). The velocity used by the CDC was determined by dividing the flow rate by the area of the respirator ($A_{3M-1860}$).

$$velocity_{3M-1860} = \frac{85 \times 16.67 \text{ cm}}{A_{3M-1860} \text{ s}}$$

Here $A_{3M-1860}$ is expressed in cm^2 and 16.67 is the conversion factor required to convert L/minute to cm^3/s . The corresponding flow rate, Q , required in our pressure rig that uses a 2.5 cm cross sectional coupon that would give the same amount of velocity is then given by

$$Q_{\text{pressure-rig}} = \frac{velocity_{3M-1860} \times \pi \frac{(2.5)^2}{4}}{16.67} \frac{\text{L}}{\text{minute}}$$

The bar plot of the CDC data and data obtained for the same respirator model with our pressure rig is shown in Figure 7. An unpaired two-tailed student t-test (GraphPad Software; San Diego, CA) ($n=3$) between the two means yielded a p-value 0.7892 ($\alpha = 0.05$) implying no statistically significant difference between CDC data and predictions by our pressure rig. A similar validation study performed with another model (3M 8210) was also not found to be statistically significant ($p=0.0677$) from 3M 8210+ measurements made by CDC. The baseline offset for the flow rate measurements were $1.62 \pm 0.01\%$ ($n=3$), and the average leak was 2.09% after correcting for the averaged offset.

CONCLUSIONS

The Face coverings continue to play an important role in reducing the transmission of COVID-19. New standards such as ASTM F3502-21 have been created to harmonize the filtration efficiency and pressure drop of face coverings. While filtration efficiency measurements require specialized equipment, by modifying an existing standardized approach we have developed a methodology of measuring pressure drop without using sophisticated instruments thus making this method more accessible to the public.

Assuming 3D printers are routinely available in the community, in case of future shortages of medical grade masks, we hope that the easy access of our pressure rig tool will promote making of breathable masks from household fabrics. We also hope that the simplicity of the pressure rig, as well as the easy availability of all the necessary components would make this tool accessible to the public with basic engineering knowledge, to hospitals, or even to stakeholders interested in scaling up production of masks from household fabrics. The pressure rig can also be used to create a repository of pressure drops for multiple common household fabrics so the public can make informed choices when making their face coverings.

Precautions and Future Improvements

The coupons used for our validation testing were not from the same lot as those used by CDC. A cross-laboratory study using same lots of respirators for further validation of the pressure rig may be desirable.

Unlike some other pressure drop measurement standards that are used particularly for the medical masks, this pressure rig is too small to fit the entire mask. Therefore, if spatial variability in pressure drop is expected in samples, multiple coupons for the same filter may need to be measured. An additional limitation is that the set up does not have capability to control the humidity.

Thick filter materials (e.g. three or four layers of tightly knit cotton, or four layers of some respirators) can be hard to tighten with this rig. A compression mechanism like utilizing a hold down clamp can be explored in future design iterations.

A limitation of the thicker filter materials can also result in micro-leak sites appearing at the filter material – 3D part interface that a simple tightening of the screws cannot overcome. In addition, the offset of the flow meter and the mass flow controller is likely to also be $> 5\%$. Gaskets thicker than those used here (3/32") can help with such sealing, but it would require additional tightening of the sample inside the

holder. Excessive tightening can be particularly problematic when handling samples that are prone to tearing such as cellulose type materials (e.g. tissue paper, paper towel etc.).

Although the difference between flow rate read out between the flow meter and the mass flow controller were below < 5% for all sample reported here, the offset can further be reduced by using epoxied fittings. In addition, the readouts from the flow meter and the flow controller can also be recorded and saved in the computer instead of manually noting the readouts for verification.

Another improvement can be logging of both the flow meter and flow controller in combination with the pressure transducers. This can allow for better analytics of how much the setup is leaking air at a given moment in time that can then be used to determine the true air velocity for the specific sample. We note that the MATLAB script in its current form can only analyze acquired data from multiple samples one flowrate at a time and assumes that all text files with a specific nomenclature in the same folder are pressure logging files and were run at that specific flowrate. Therefore, saving other unrelated text files in the same folder should be avoided.

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Disclaimer

The Department of Health and Human Services does not promote nor endorse any of the materials or instruments used here. The findings and conclusions of this paper are solely the authors' and do not represent the official position of the Food and Drug Administration. The methodology discussed here does not change the regulatory requirements or test methods necessary for clearance of FDA regulated medical devices such as surgical masks, pediatric face masks, and surgical respirators.

Declaration of Interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Supplementary Material

Supporting information provides the STL file of our 3D printed pressure rig, the Python and MATLAB scripts and functions for data acquisition and analysis.

REFERENCES

- ASTM. (2021) Standard Specification for Barrier Face Coverings. ASTM. West Conshohocken, PA. ASTM F3502-21.
- Bartoszko JJ, Farooqi MAM, Alhazzani W, Loeb M. (2020) Medical masks vs N95 respirators for preventing COVID-19 in healthcare workers: A systematic review and meta-analysis of randomized trials. *Influenza Other Resp.* 14(4):365-73.
- British Standards Institution. (2009) Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking. British Standards Institution. London, UK. BS EN 149:2001+A1:2009.
- British Standards Institution. (2019) Medical face masks. Requirements and test methods. British Standards Institution. London, UK. BS EN 14683:2019+AC:2019.
- Carr IH, Hariharan P, Guha S. (2020) Letter to the Editor Regarding Aerosol Filtration Efficiency of

- Common Fabrics Used in Respiratory Cloth Masks. *ACS Nano*. 14(9):10754–5.
- Center for Disease Control. (2021) Use Masks to Slow the Spread of COVID-19. Center for Disease Control. Atlanta, GA. Available: <https://go.usa.gov/xeaMz>.
- Coffey CC, Lawrence RB, Campbell DL, Zhuang Z, Calvert CA, Jensen PA. (2010) Fitting Characteristics of Eighteen N95 Filtering-Facepiece Respirators. *J Occup Environ Hyg*. 1(4):262-71.
- Greenawald L, Moore S, Yorio P, and Wizner K. (2020) PPE CASE: Inhalation and Exhalation Resistance and Filtration Performance of Stockpiled Air-Purifying Respirators: Facility One of Ten. National Institute for Occupational Safety and Health. Pittsburgh, PA. NPPTL Report Number P2020-0101
- Kim JH, Wu T, Powell JB, Roberge RJ. (2016) Physiologic and fit factor profiles of N95 and P100 filtering facepiece respirators for use in hot, humid environments. *Am J Infect Control*. 44(2):194-8.
- Konda A, Prakash A, Moss GA, Schmoldt M, Grant GD, Supratik G. (2020) Aerosol Filtration Efficiency of Common Fabrics Used in Respiratory Cloth Masks. *ACS Nano*. 14(5):6339-47.
- National Institute for Occupational Safety and Health. (2019a) Determination of Inhalation Resistance Test, Air-Purifying Respirators Standard Testing Procedure. National Institute for Occupational Safety and Health. Pittsburgh, PA. TEB-APR-STP-0007.
- National Institute for Occupational Safety and Health. (2019b) 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. Pittsburgh, PA. TEB-APR-STP-0059.
- Radonovich LJ, Jr., Simberkoff MS, Bessesen MT, Brown AC, Cummings DAT, Gaydos CA, et al. (2019) N95 Respirators vs Medical Masks for Preventing Influenza Among Health Care Personnel: A Randomized Clinical Trial. *JAMA*. 322(9):824-33.
- Roberge RJ, Kim JH, Benson S. (2012) N95 filtering facepiece respirator deadspace temperature and humidity. *J Occup Environ Hyg*. 9(3):166-71.
- Rottach D, Susan X, McClain, C, King W. (2020) Simple physical modeling for comparing respirator breathing resistance standards. *Bulletin of the American Physical Society*, Denver, CO, 65(1):C71.
- Schneider C, Rasband W, and Eliceiri K. (2012) NIH Image to ImageJ: 25 years of image analysis. *Nat Methods*. 9(7): 671–5
- Shykoff B, Warkander D, Winters D. (2010) Exercise Limitation Imposed by an Approved Air Purifying Respirator (APR). Navy Experimental Diving Unit, Panama City, FL. NEDU Technical Report No. TR 10-06.
- Quinn, T., Bergman M., Strickland, K., Streeter, R., Vollmer, B., Meyers, J., Wilson, A., Pollard, J.P. (2020) PPE CASE: Assessment of Filter Penetration Performance and Fit for Decontaminated N95 Respirators: Report 25 - 3M 8210+. National Institute for Occupational Safety and Health. Pittsburgh, PA. NPPTL Report Number P2021-0101, Report 25.