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E-mail: jhenry@airespaworldwide.com 26 May 2020

J Henry Scott
Founder
Medify Air, LLC
8 The Green
Dover, DE 19901
USA
Phone: +1(908)227-4441

Re: H-13 HEPA Filter Performance

Dear Mr. Scott:

Intertek appreciates the continued strategic and collaborative partnership with Medify Air and the confidence you have placed in us to conduct an independent, third party evaluation of internationally testing methodologies of high efficiency air particulate air (HEPA) filters.

Attached is the requested report that summarizes our research of the peer-reviewed literature regarding the efficacy of use of HEPA filters in microenvironment applications. As cited in the body of this report, we have determined that for those applications that require certified HEPA filtration in order to meet indoor air quality standards, where filters are tested in accordance with American Society of Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE) and International Organization for Standardization (ISO) standards, there is objective evidence that portable HEPA filtration systems may be used to capture airborne pathogens.
.

Best Regards,

Robert J. Steele, PhD., PMP
Contract Consultant
Intertek Assurance
1809 10th St. Suite 400
Plano, TX 75074

Consultative Report

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Revision 0

Issued: May 26, 2020

Prepared for:

Medify Air, LLC
8 The Green
Dover, DE 19901

Issued by:

Intertek Assurance.
1809 10th St Suite 400,
Plano, TX 75074

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SCOPE

Intertek Assurance was commissioned as an independent-third party to conduct a review of the relevant international consensus standards and peer-reviewed (or refereed) publications to evaluate the applicability of the Medify Air Purification systems as high efficiency particulate air (HEPA) H-13 residential filtration systems to determine the theoretical airborne viruses capture.

This report exercises due diligence by evaluating North American and international consensus testing standards and evaluates general laboratory testing requirements by which a certification agency would apply to residential air filtration systems. Those international consensus standards referencing "in-place" or "in-situ" do not typically apply to HEPA H-13 residential filters and are not in the scope of this third-party, independence evaluation. The Medify findings of this research are presented herein.

This report cites refereed publications on typical bacterial and viruses, that if suspended in air, could be used as supplemental protective measures to minimize the likelihood airborne viruses

PURPOSE

The purpose of this research is to present the international consensus standards and referred publications that delineate performance and effectiveness of HEPA filter testing aerosols as a function of the intended application. This research focuses on the applicability of HEPA H-13 filters, and the associated testing, for the residential sector. This research does not evaluate HEPA filter testing methodology used in the industrial or commercial market sectors.

The intent of this research is to present the findings and relevant studies conducted to characterize residential air filtration systems and to summarize the technical performance basis by a which HEPA H-13 filters could capture typical residential airborne particulates, contaminants including potentially suspended bacterial and viruses.

OVERVIEW

This report includes the following basic elements, in this order:

- Cover Letter
- Title Page
- Report Body

APPLICATION OF INTERNATIONAL CONSENSUS STANDARDS

It is generally understood within the engineering community, the requirements within international consensus standards may not apply to every application. Therefore, in the absence of specifically applicable international consensus standards, the filtration system user/engineer is obligated to identify how any deviation from the minimum requirements within the standard of record, is objectively satisfied (or exceeds the minimum criteria) using the best available information for the intended application. This situation applies to those residential air

cleaning systems when HEPA filters are required by the owner/operator to understand the application requirement and implement appropriate mitigation measures for microenvironment air filtration [1].

It is known and well documented however, that the Institute of Environmental Science and Technology (IEST) Testing Standards are intended to test HEPA filters that are acceptable for cleanrooms and clean spaces that fall within the scope of the ISO 14644 series standards. Understanding that HEPA filters are not only used in clean rooms, IEST also provides recommendations for the application of HEPA filters as a function of risk including, but not limited to, radiological, nuclear, biological, pharmaceutical, industrial, chemical, micro-electronic and aerospace applications. IEST recognizes that their standards are not intended to be inclusive of every potential application and states "and determination of its applicability and suitability for any particular use is solely the responsibility of the user… Information and other standards on the topic covered by this publication may be available from other sources, which the user may wish to consult for additional views or information not covered by this publication" [1].

The IEST series standard identifies 11 different HEPA filter performance levels as a function of risk and provides application recommendations to assist the Application Engineer. IEST standards do not address the minimum HEPA performance requirements for residential applications. Therefore, using recognized and generally accepted good engineering practice, this report evaluates the minimum criteria for HEPA filters for indoor microenvironments (residential) using best available information and integrates supplemental information not covered by the IEST standards.

REPORT

Over the last several decades, the quality of indoor air has been gaining significant attention from the medical community where the cleaning of the air has gained significant attention due to indoor habitation and the associated respiratory problems [2-5]. Improvements in home construction has resulted in an increase of people spending more than 85% of their time in indoor microenvironments. According to the research conducted as part of this study, 62 – 87% of the day is spent in the residential or office microenvironments which has a direct correlation to the daily total personal exposure of airborne viruses and contaminants [6].

Therefore, in order to identify the type of HEPA filtering needed to improve the air quality of residential and microenvironments, an understanding of the air properties and air quality standards is necessary.

Air Quality Standards

The United States Environmental Protection Association (EPA) recognizes ASHRAE for establishing national consensus standards for indoor and outdoor air quality for microenvironments [7]. Refer to ASHRAE Standard 62.2 for specific indoor air quality requirements [8]. The *ASHRAE Handbook: HVAC Systems and Equipment* provides the following recommended criteria of the sizing and selection of the appropriate filtration for each application in Article 3, Selection and Maintenance and states:

> "To evaluate filters and air cleaners properly for a particular application, consider the following factors:
>
> - Types of contaminants present indoors and outdoors

- Sizes and concentrations of contaminants
- Air cleanliness levels required in the space
- Air filter efficiency needed to achieve cleanliness
- Space available to install and access equipment
- Life-cycle costing, including
  - Operating resistance to airflow (static pressure differential)
  - Disposal or cleaning requirements of spent filters
  - Initial cost of selected system
  - Cost of replacement filters or cleaning
  - Cost of warehousing filter stock and change-out labor" [9]

The following discussion systematically follows the ASHRAE selection guidelines to determine the appropriate HEPA filter and associated testing for residential applications.

Microenvironment Air Properties (Contaminants)

As indicated by the ASHREA Handbook, the first step in the proper use of air filters and cleaners is the characterization of the environment where the Medify Air Purifier may be used. It is assumed the Medify Air Purifier is not used in a radiological, nuclear, biological, pharmaceutical, industrial, chemical, micro-electronic and aerospace applications. It is assumed the Medify purifiers are typically used in residential micro-environments.

Residential air is a highly complex relationship between inherent human daily activity, construction material, and the dynamic relationship of indoor to outdoor exchange. The following discussion presents the research of indoor air quality and is inclusive of airborne bacteria and viruses that could be entrained into the air stream and potentially captured by a certified H-13 HEPA Filter.

Indoor – Outdoor Air Relationships and Size of Contaminants

Indoor air quality and the dynamic exchange of airborne contaminants has been well studied and documented [2, 3, 5, 6, 8, 10-31]. Inherently, there is continuous air exchange between indoor environments and the outdoors due to diurnal changes and human activity that results in outdoor particulates and emissions readily infiltrating into indoor environments. Conversely, indoor emissions seep outdoors and can contribute to outdoor air pollution [24]. For most Americans, vehicles are the primary means of the multimodal transportation and resultant fine particles and other emissions from nearby motor vehicles typically penetrate indoor environments to varying degrees, depending on the rate of air exchange, degree of filtration, and other factors [24, 32]. In many cases, and based upon seasonal changes, the main entry routes of the infiltration of outdoor air into the microenvironments are through open windows and doors, design and construction discrepancies, and differential pressures created by the heating, ventilation, and cooling (HVAC) systems. It is well documented that indoor pollutant levels can be much higher than those outdoors when indoor sources are present and the air exchange rate is low [24]. Indoor microenvironments are further contaminated by the off-gassing and decay of plants, food products, paints, consumer products, and gas and wood-burning appliances that contribute to both indoor and outdoor pollution levels [24].

The research conducted by Wallace identified four primary indoor activities that generated peak concentrations of small diameter airborne particulates (about 10 nm or less) and evaluated their impact to indoor air quality [31]. These activities included the preparation of tea, tea and toast, typical breakfast activities, and the use of a gas clothes dryer. In each, the bulk of the particles were supplied by nearly pure natural gas burning.

Additionally, Wallace evaluated the impact of more complex cooking, such as using the gas burners to cook dinner, stir-fry vegetables, and fry eggs, resulting in airborne particulates of approximately 36–40 nm. Also noted that cooking involving the gas oven (broiling fish, baking potatoes) produced airborne particles in much higher diameters (45–46 nm). It was also found that deep frying tortillas followed by baking them in the oven resulted in the generation of particles approximately 64 nm. These findings were systematically measured against outdoor particulates infiltrating the indoor microenvironment where those approximately 69 nm were realized. Wallace found that indoor airborne particles ranged from 46 nm for making tea to 638 nm for burning a candle [31]. The results of his measurements are presented in Table 1.

Table 1

Size-resolved particle volume (μm/cm)^{3}due to 18 activities

	Diameter (nm)				
Activity	10–100	100–200	200–450	450–950	Total
Tea	0.08	0.06			0.14
Tea & toast	0.18				0.18
Breakfast	0.46	0.10		1.19	1.74
Gas clothes dryer	0.87	0.89	0.44	0.61	2.81
Open windows	0.59	1.17	1.28	0.52	3.56
Unknown indoor sources	1.11	1.31	0.88	1.46	4.76
No indoor sources	0.26	1.01	1.99	1.81	5.07
Stir-fry	1.51	1.82	1.20	2.08	6.62
Gas oven	2.15	1.42	1.02	2.72	7.31
Outdoors	0.88	2.53	2.72	1.80	7.62
Unknown outdoor source	0.64	1.49	2.52	3.68	8.32
Broiled fish	3.54	2.77	0.88	2.43	9.61
Incense	0.69	3.67	6.74		11.10
Dinner	1.94	2.97	3.34	4.68	12.93
Fried eggs	1.55	2.89	3.43	6.31	14.18
Tortillas	5.01	10.54	7.26	8.53	31.35
Smoky cooking oil	4.71	11.52	16.95	15.39	48.57
Citronella candle	0.25	2.99	24.29	70.96	98.50

The findings of Wallace are consistent with those presented by the American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) and Sutherland [33, 34]. Figure 1 presents the research conducted by ASHRAE and Figure 2 presents the findings from Sutherland.

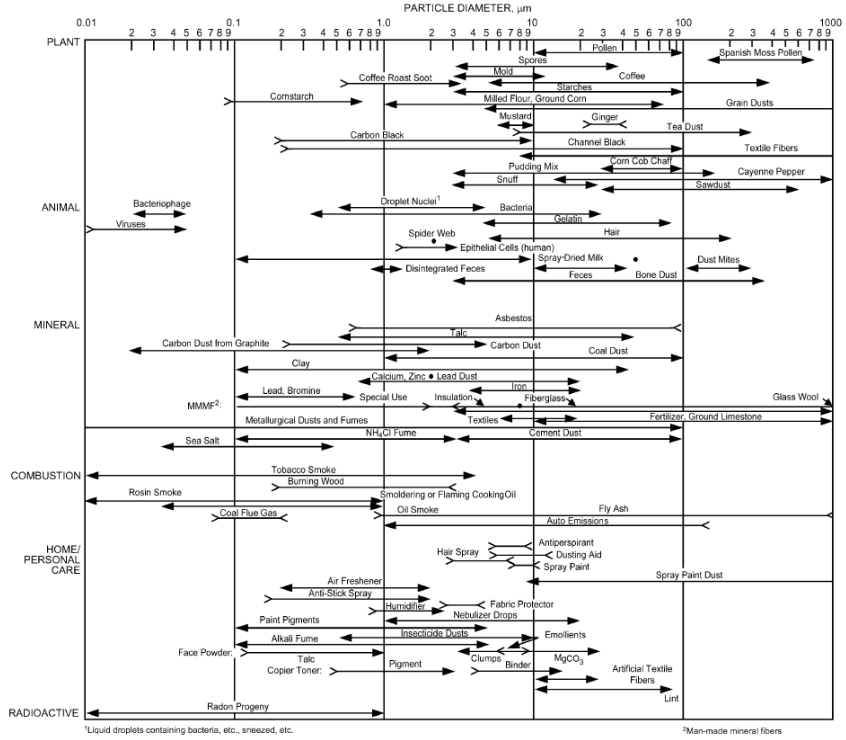

Figure 1: Size of Indoor Air Particles[33]

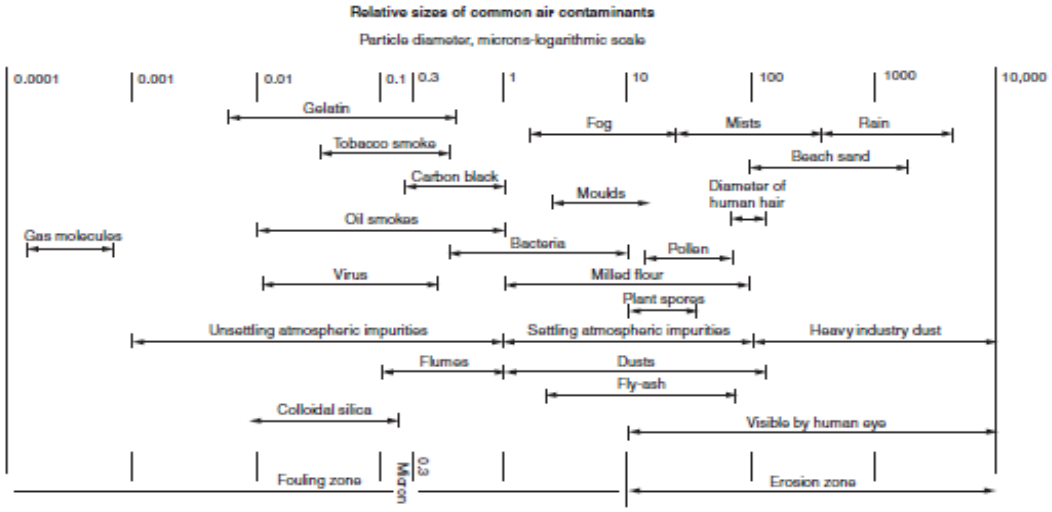

Figure 2: Common Air Contaminants [34]

Bio-Aerosolized Pathogens

It is well documented the airborne transmission of infectious diseases can result in contagion of smallpox, tuberculosis, and severe acute respiratory syndrome (SARS) [35]. Beggs's study in microenvironments concluded that the contribution of airborne pathogens to the spread of infection is likely to be underestimated currently although contact-spread is the principal route of transmission for most infections [36]. Airborne transmission is deemed as long-range aerosol transmission, which refers to the situation that agents can be carried long distances

(within a room or between rooms, generally greater than 1m) by forced ventilation air flows [37]. Recent lessons learned from the 2003 SARS outbreak and the threats and other potential pandemics indicates correlation in microenvironments. Li et al. reviewed over 40 studies on the relationship between the transmission of infection and ventilation systems in microenvironments and concluded 25% causation between ventilation and transmission of airborne infection [38]. This literature review indicates sufficient evidence to demonstrate the association between ventilation, indoor air movements and the transmission of infectious respiratory diseases and pathogens [39-47].

Significance of Aerosolized Particle Size

Aerosolized transmission of infectious diseases can be classified as either droplet or airborne transmission [38, 42, 48]. Droplet transmission is defined as the transmission of diseases by expelled particles that have a propensity to settle quickly to the ground, usually within 1 m of the site of generation, due to their size [49, 50]. Therefore, the potential infection due to droplet transmission is a function of distance and proximity between infected and target host and direct contact and conveyance between the infected droplet respiratory tract of a susceptible host. Settled droplets may also facilitate fomite transmission of infection [48].

Conversely, airborne transmission is defined as the transmission of infection by expelled particles that are comparatively smaller in size and potentially remain suspended in the air for prolonged periods and thereby potentially expose a greater number of susceptible individuals to possible infection at a greater distance from the source [51, 52]. The correlation between droplet and airborne transmission has been well documented by Wells [49], identified the interdependence of settling of expelled particles as being a function of size, time and evaporation. Additionally, the work of Hamburger and Robertson, whom described the distance travelled by particles expelled during sneezing and coughing events as a function of time [53].

“Particle size governs the transport of virus aerosol, its deposition in the human respiratory tract, as well as its control by filtration. Particle size may also play a role in the minimum infectious dose of a given virus. For instance, small-sized aerosol inhalation of human influenza virus and adenovirus yielded a much lower median infectious dose than intranasal inoculation with droplets of much larger size” [54]. Particle size also determines the distance across which pathogens can be transported, as well as the site of deposition and the survivability of the pathogen [55].

The conveyance of influenza virus between humans typically occurs via three routes: (1) direct or indirect contact between an infected and a susceptible person, usually resulting in contamination of a susceptible person’s hands followed by hand to respiratory mucosa contact; (2) large droplet spray wherein droplets of respiratory fluid greater than approximately 100 mm in diameter are expelled with sufficient momentum to deliver a direct hit on the respiratory mucosa; and (3) aerosols generated by release of smaller, virus containing droplets, as may occur during tidal breathing and coughing, that rapidly evaporate into residual particles (droplet nuclei),which are inhaled and deposited in the respiratory tract[56].

Based on the aforementioned studies and the significance of an aerosolized pathogen, Table 2 is provided as a reference to typical viruses within microenvironments.

Table 2: Airborne Respiratory Pathogens—Sizes and Dimensions [48]

AIRBORNE PATHOGEN	AVG DIA	DIA/WIDTH		LENGTH		AR	EQUIV DIA	LOGMEAN DIAMETER	LN STDEV
		MIN	MAX	MIN	MAX				
Parvovirus B19	0.022	0.018	0.026			1		0.022	0.074
Rhinovirus	0.023	0.018	0.028			1		0.022	0.088
Coxsackievirus	0.025	0.02	0.03			1		0.024	0.081
Echovirus	0.025	0.02	0.03			1		0.024	0.081
Hantavirus	0.06	0.05	0.07			1		0.059	0.067
Togavirus	0.063	0.05	0.075			1		0.061	0.081
Reovirus	0.073	0.07	0.075			1		0.072	0.014
Adenovirus	0.08	0.07	0.09			1		0.08	0.050
Orthomyxovirus	0.1	0.08	0.12			1		0.10	0.081
Coronavirus	0.11	0.08	0.13			1		0.10	0.097
Varicella-zoster	0.15	0.1	0.2			1		0.14	0.139
Arenavirus	0.18	0.05	0.3			1		0.12	0.358
Francisella tularenis	0.19	0.08	0.3	0.2	0.7	2.4	0.13	0.15	0.264
Morbillivirus	0.2	0.1	0.3			1		0.17	0.220
Respiratory Syncytial Virus	0.22	0.14	0.3			1		0.20	0.152
Parainfluenza	0.23	0.15	0.3			1		0.21	0.139
Poxvirus - Vaccinia	0.23	0.2	0.25	0.25	0.3	1.2	0.08	0.22	0.045
Mycoplasma pneumoniae	0.23	0.15	0.3			1		0.21	0.137
Paramyxovirus	0.23	0.15	0.31			1		0.22	0.145
Bordetella pertussis	0.25	0.2	0.3	0.5	1	3	0.21	0.24	0.081
Chlamydia pneumoniae	0.3	0.2	0.4			1		0.28	0.139
Chlamydia psittaci	0.3	0.2	0.4			1		0.28	0.139
Klebsiella pneumoniae	0.4	0.3	0.5			1		0.39	0.102
Haemophilus influenzae	0.43	0.2	0.3	1	1.5	5	0.43	0.35	0.081
Coxiella burnetii	0.5	0.45	0.55			1		0.50	0.040
Pseudomonas aeruginosa	0.57	0.3	0.8	1	3	3.6	0.57	0.51	0.209
Pseudomonas pseudomallei	0.57	0.3	0.8	1	3	3.6	0.57	0.51	0.209
Actinomyces israelii	0.6	0.2	1	2	5	5.8	1	0.90	0.183
Legionella pneumophila	0.6	0.3	0.9	2	2	3.3	0.57	0.72	0.091
Thermomonospora viridis	0.6	0.3	0.9	0.6	1.5	1.8	0.30	0.52	0.220
Cardiobacterium	0.63	0.5	0.75	1	3	3.2	0.57	0.65	0.107
Micropolyspora faeni	0.69	0.66	0.72			1		0.7	0.017
Thermoactinomyces sacchari	0.7	0.6	0.8	1	3	2.9	0.57	0.72	0.071
Mycobacterium kansasii	0.71	0.2	0.6	1	4	6.3	0.71	0.57	0.277
Alkaligenes	0.75	0.5	1	0.5	2.6	2.1	0.44	0.71	0.139
Yersinia pestis	0.75	0.5	1	1	2	2	0.43	0.71	0.139
Pseudomonas mallei	0.77	0.3	0.8	1.4	4	4.9	0.77	0.67	0.210
Neisseria meningitidis	0.8	0.6	1			1		0.77	0.102
Streptococcus pyogenes	0.8	0.6	1			1		0.77	0.102
Mycobacterium tuberculosis	0.86	0.2	0.6	1	5	7.5	0.86	0.64	0.322
Staphylococcus aureus	0.9	0.8	1			1		0.89	0.045
Streptococcus pneumoniae	0.9	0.8	1			1		0.89	0.045

Corynebacteria diphtheria	1	0.3	0.8	1	6	6.4	1.0	0.72	0.348
Haemophilus parainfluenzae	1	0.75	1.25			1		0.97	0.102
Moraxella lacunata	1	0.8	1.2	1.5	3	2.3	0.64	0.98	0.081
Micromonospora faeni	1	0.5	1.5			1		0.87	0.220
Thermoactinomyces vulgaris	1	0.5	1.5			1		0.87	0.220
Bacillus anthracis	1.13	1	1.25			1		1.12	0.045
Nocardia asteroides	1.14	1	1.25	3	5	3.6	1.14	1.19	0.071
Mycobacterium avium	1.2	1.075	1.325			1		1.19	0.042
Mycobacterium intracellulare	1.2	1.075	0.325			1		1.2	0.042
Acinetobacter	1.25	1	1.5	1.5	2.5	1.6	0.57	1.22	0.081
Moraxella catarrhalis	1.25	1	1.5	2	3	2	0.71	1.22	0.081
Serratia marcescens	1.25	1	1.5	2	6	3.2	1.14	1.31	0.107
Nocardia brasiliensis	1.5	1	2			1		1.41	0.139
Nocardia caviae	1.5	1	2			1		1.41	0.139
Phialophora spp.	1.5	1.20	1.8	3	4	2.3	1.0	1.5	0.081
Pneumocystis carinii	2	1	3			1		1.7	0.220
Acremonium spp.	2.5	2	3	4	6	2	1.43	2.4	0.081
Geomyces pannorum	3	2	4	2	5	1.2	1.0	2.8	0.139
Histoplasma capsulatum	3	1	5			1		2.2	0.322
Paecilomyces variotii	3	2	4	3	5	1.3	1.14	2.8	0.139
Wallemia sebi	3	2.5	3.5			1		3.0	0.067
Emericella nidulans	3.25	3	3.5			1		3.2	0.031
Phoma spp.	3.25	2.5	4	6	10	2.5	2.28	3.2	0.094
Penicillium spp.	3.3	2.8	3.8	3	4	1.1	1.0	3.3	0.061
Aspergillus spp.	3.5	2.5	4.5			1		3.4	0.118
Absidia corymbifera	3.75	2.5	5			1		3.5	0.139
Coccidioides immitis	4	2	6			1		3.5	0.220
Trichoderma spp.	4.1	3.6	4.5			1		4.0	0.045
Rhizomucor pusillus	4.25	3.5	5			1		4.2	0.071
Aureobasidium pullulans	5	4	6	8	12	2	2.85	4.9	0.081
Chaetomium globosum	5.5	4.8	6.2	5.9	6.8	1.2	1.81	5.5	0.051
Cryptococcus neoformans	5.5	5	6			1		5.5	0.036
Stachybotrys spp.	5.65	5.1	6.2			1		5.6	0.039
Eurotium spp.	5.75	4.5	7			1		5.6	0.088
Scopulariopsis spp.	6	5	7	5	8	1.1	1.85	5.9	0.067
Sporothrix schenckii	6.5	5	8	10	20	2.30	4.28	6.3	0.094
Botrytis cinera	7	5	9	7	14	1.5	2.99	6.7	0.118
Mucor plumbeus	7.5	5	10			1		7.1	0.139
Rhizopus stolonifer	8	4	12			1		6.9	0.220
Cladosporium spp.	9	5	13			1		8.1	0.191
Fusarium spp.	11.5	9	14			1		11.2	0.088
Helminthosporium	12.5	7.5	8.8	27.5	60	5.4	12.47	11.6	0.156
Blastomyces dermatitidis	14	8	20			1		12.6	0.183
Rhodoturula spp.	14	12	16			1		13.9	0.058
Alternaria alternata	14.4	7	18	18	83	4	14.39	12.9	0.244

Ulocladium spp.	15	10	20			1		14.1	0.139
Paracoccidioides brasiliensis	18.25	6.5	30			1		14.0	0.306

Air Cleanliness Levels

Following the guidance of ASHRAE, the third step in determining the appropriate filtration is the establishment of the air cleanliness levels.

Understanding the air filtration industry has undergone numerous recent changes due to technological advances and the HEPA filter design, construction, and testing methodologies, the selection of the correct HEPA filter for the residential/microenvironment application is not unambiguous. Therefore, to assist HVAC engineers and consumers in the selection of the appropriate filtration for the application, the EPA and ASHRAE have provided appropriate selection guidelines and are presented in Table 3.

The following discussion presents the Indoor Air Quality Standard identified by EPA and the associated standards including ANSI/ASHRAE Standard 62.1 and ANSI/ASHRAE 62.2 [7, 8, 11].

ANSI/ASHRAE 62.1: Ventilation for Acceptable Indoor Air Quality

ANSI/ASHRAE Standard 62.1 is designed to specify minimum ventilation rates and other measures intended to provide indoor air quality that is acceptable to human occupants and that minimizes adverse health effects. ASHRAE 62.1 is intended to outline the regulatory application of normative requirements for new buildings, additions to existing buildings, and modifications to existing buildings. It is intended to assist qualified and competent engineers as a guide for the improvement of indoor air quality in existing buildings and applies to "all spaces intended for human occupancy except those within single-family houses, multifamily structures of three stories or fewer above grade, vehicles, and aircraft" [11]. It is important to note that ASHRAE 62.1 provides the ventilation requirements based on chemical, physical, and biological contaminants that can affect air quality[11].

Table 6-1 of ASHRAE 62.1 specifies the minimum air quality for residential microenvironments and states in part:

Table 3Minimum Ventilation Rates in Breathing Zone (partial)[11]

Occupancy Category	People Outdoor Air Rate R_p		Area Outdoor Air Rate R_a		Notes	Default Values			Air Class
						Occupancy Density (see Note 4)	Combined Outdoor Air Rate (see Note 5)		
	Cfm/person	L/s person	Cfm/ft^2	L/s m^2		#/1000ft^2 or #/100 m^2	Cfm/person	L/s person	
Dwelling unit	5	2.5	0.06	0.3	F				1
Common corridors	-	-	0.06	0.3	F,G				1

Article 5.9 of ASHRAE 62.1 provides the guidelines for minimum requirements for particulate matter (PM) removal. ASHRAE recommends that in order to achieve the minimum air cleanliness that **"**[particulate] matter filters or air cleaners having a minimum efficiency reporting value (MERV) of not less than 6 when rated in accordance with ANSI/ASHRAE Standard 52.2 shall be provided upstream of all cooling coils or other devices with wetted surfaces through which air is supplied to an occupiable space" [11].

Although the minimum air cleanliness guidelines state that indoor air quality guidelines shall not have a MERV rating of less than 6, the remainder of this discussion focuses on the application of HEPA filtration and the required testing aerosol to exceed the minimum requirements of ASHRAE 62.1 and rated in accordance with ANSI/ASHRAE Standard 52.2. MERV ratings are presented in Table 4.

ANSI/ASHRAE Standard 62.2: Ventilation and Acceptable Indoor Air Quality in Residential Buildings

ANSI/ASHRAE 62.2 defines the characteristics of the performance of, and minimum requirements for, mechanical and natural ventilation systems and the building envelope intended to provide acceptable indoor air quality (IAQ) in residential buildings [8]. Air quality requirements are presented throughout ASHRAE 62.2 however, filtration requirements are presented in Section 6.7, *Minimum Filtration*.

ASHRAE 62.2, Section 6.7 states "[mechanical] systems that supply air to an occupiable space through ductwork exceeding 10 ft (3 m) in length and through a thermal conditioning component, except evaporative coolers, shall be provided with a filter having a designated minimum efficiency of MERV 6 or better when tested in accordance with ANSI/ASHRAE Standard 52.2, *Method of Testing General Ventilation Air-Cleaning Devices for Removal Efficiency by Particle Size* 12, or a minimum Particle Size Efficiency of 50% in the 3.0 to 10 µm range in accordance with AHRI Standard 680, *Performance Rating of Residential Air Filter Equipment*. The system shall be designed such that all recirculated and mechanically supplied outdoor air is filtered before passing through the thermal conditioning components. The filter shall be located and installed in such a manner as to facilitate access and regular service by the owner" [8].

Therefore, the normative requirement for indoor air quality standards does not mandate any additional filtration mechanisms. Inclusion of additional air purification systems such as the suit of the products available by the Medify Air is at the discretion of the user.

Table 4: ASHRAE Filter Performance Guidelines [57]

Table E-1 Application Guidelines

Std. 52.2 Minimum Efficiency Reporting Value (MERV)	Application Guidelines		
	Typical Controlled Contaminant	Typical Applications and Limitations	Typical Air Filter/Cleaner Type
16	**0.30 to 1.0 µm Particle Size**	Hospital inpatient care	**Bag Filters**
	All bacteria	General surgery	Nonsupported (flexible) microfine fiberglass or synthetic
15	Most tobacco smoke	Smoking lounges	media. 300 to 900 mm (12 to 36 in.) deep, 6 to 12 pockets.
	Droplet nuclei (sneeze)	Superior commercial	**Box Filters**
14	Cooking oil	buildings	Rigid style cartridge filters 150 to 300 mm
	Most smoke		(6 to 12 in.) deep may use lofted (air laid) or paper (wet laid)
13	Insecticide dust		media.
	Copier toner		
	Most face powder		
	Most paint pigments		
12	**1.0 to 3.0 µm Particle Size**	Superior residential	**Bag Filters**
	Legionella	Better commercial	Nonsupported (flexible) microfine fiberglass or synthetic
11	Humidifier dust	buildings	media. 300 to 900 mm (12 to 36 in.) deep, 6 to 12 pockets.
	Lead dust	Hospital laboratories	**Box Filters**
10	Milled flour		Rigid style cartridge filters 150 to 300 mm
	Coal dust		(6 to 12 in.) deep may use lofted (air laid) or paper (wet laid)
9	Auto emissions		media.
	Nebulizer drops		
	Welding fumes		
8	**3.0 to 10.0 µm Particle Size**	Commercial buildings	**Pleated Filters**
	Mold	Better residential	Disposable, extended surface, 25 to 125 mm
7	Spores	Industrial workplaces	(1 to 5 in.) thick with cotton-polyester blend media,
	Hair spray	Paint booth inlet air	cardboard frame.
6	Fabric protector		**Cartridge Filters**
	Dusting aids		Graded density viscous coated cube or pocket filters,
5	Cement dust		synthetic media.
	Pudding mix		**Throwaway**
	Snuff		Disposable synthetic media panel filters.
	Powdered milk		
4	**>10.0 µm Particle Size**	Minimum filtration	**Throwaway**
	Pollen	Residential	Disposable fiberglass or synthetic panel filters
3	Spanish moss	Window air conditioners	**Washable**
	Dust mites		Aluminum mesh, latex coated animal hair, or foam rubber
2	Sanding dust		panel filters
	Spray paint dust		**Electrostatic**
1	Textile fibers		Self charging (passive) woven polycarbonate
	Carpet fibers		panel filter

Note: A MERV for other than HEPA/ULPA filters also includes a test airflow rate, but it is not shown here because it has no significance for the purposes of this table.

HEPA Filter Selection Criteria, Performance Properties, and Testing Aerosol

The fourth step in determining the proper air filtration or purification recommended by ASHRAE is the selection of air filter efficiency needed to achieve desired cleanliness.

ASHRAE Standard 52.2 provides the performance standards and characteristics of ventilation system filtration guidelines for the removal of particles from the airstream and its resistance to airflow. Air-cleaning system testing is conducted at airflow rates not less than 0.22 m3/s (472 cfm) nor greater than 1.4 m3/s (3000 cfm). ASHRAE 52.2 establishes a test procedure for evaluating the performance of air-cleaning devices as a function of particle size. [57].

ASHRAE Std. 52.2 "describes a method of laboratory testing to measure the performance of general ventilation air-cleaning devices. The method of testing measures the performance of air cleaning devices in removing particles of specific diameters as the devices become loaded by standardized loading dust fed at interval to simulate accumulation of particles during service life. The standard defines procedures for generating the aerosols required for conducting the test. The standard also provides a method for counting airborne particles of 0.30 to 10 µm in diameter upstream and downstream of the air-cleaning device in order to calculate removal efficiency by particle size" [57].

According to ASHRAE Table E-1 (Table 3 of this report), the minimum MERV rating of "superior residential" filtration systems shall have a minimum rating of 12 [57].

In order to objectively demonstrate the minimum MERV rating, ASHRAE 52.2 requires that all HEPA filters be tested using the criteria therein and use a test aerosol as defined in Section 4.3.1. Section 4.3.1 states "[the] test aerosol shall be polydisperse solid-phase (dry) potassium chloride (KCl) particles generated from an aqueous solution. The aerosol generator shall provide a stable test aerosol of sufficient concentration over the 0.30 to 10 µm diameter size range to meet the requirements of Section 10 without overloading the aerosol particle counter 4. Refer to Section 5.6" [57]. Section 5.6 of ASHRAE 52.2 outlines the requirements for concentration limits for the particle counter used to measure the filter effectiveness.

ASHRAE 52.2, Section 6.0 provides the requirements of the testing materials. Section 6.1 provides the requirements for the test aerosol and states "[The test aerosol shall be solid-phase potassium chloride (KCl) particles generated from an aqueous solution. The solution shall be prepared by dissolving reagent grade KCl in distilled water"[57].

The technical basis for the selection of KCI as the test aerosol is presented in ASHRAE 52.2, Section A.4 and states

"A4.1 Particulate potassium chloride (KCl) was chosen as the test aerosol for ASHRAE Research Project RP-671 by consensus among the project monitoring committee and the research contractor. The decision was later unanimously supported by the project committee.

A4.2 Nonsynthetic outdoor (ambient) air would have been preferred as the test aerosol but it could not be used for the following reasons:

a. It lacks a statistically significant quantity of particles >3 µm. The particle size range of this standard includes sizes up to 10 µm.

b. It is difficult to obtain reproducible test data from laboratories located in different geographical areas, or even in the same laboratory at different times, without knowing the chemical composition of the ambient aerosol and the size distribution and concentration of the aerosol and rigid control of test hardware. The project committee chose to emphasize performance parameters and relax hardware constraints.

c. High particle concentrations in sizes <3 µm could overload the particle counter, and inconsistent particle size and shape could produce measurement errors.

A4.3 Potassium chloride particles have advantages over other synthetic test aerosols because they are easy to generate, have a low cost, are commonly available, and are benign to health. Potassium chloride is also a polydisperse aerosol and has a high critical relative humidity. Commentary follows on other test aerosols that were considered.

A4.3.1 Monodisperse polystyrene latex (PSL) spheres would require a repeat of the test for each particle size of interest, significantly increasing the time to develop a 0.30 to 10 µm efficiency curve. Although

monodisperse PSL aerosols are routinely used for instrument calibration and in small scale test rigs, it is difficult to generate them in sufficient concentration for the test airflows specified in this standard.
A4.3.2 Polydisperse PSL spheres or other polydisperse particles have not been standardized or defined. One type, a latex resin, may be harder to clean up because it is not water soluble.
A4.3.3 Solid-phase aerosol particles were desired for this standard because they usually present a more severe challenge to an air cleaner. They frequently bounce off collection surfaces (e.g., fibers), increasing the chance of penetration. Particle sizes >3 µm are most likely to bounce.
A4.3.4 Sodium chloride was also considered, but it was not chosen because the relative humidity of the air must be stringently controlled at less than 55% in order to dry droplets of its solution. KCl droplets dry to solid-phase particles at a relative humidity below 70%."[57].

AHRI Standard 680: 2017 Standard for Performance Rating of Residential Air Filter Equipment [58]

AHRI Standard 680 establishes the definitions, classifications, testing requirements, rating requirements, minimum data requirements for Published Ratings, operating requirements, marking and nameplate data, and conformance conditions for residential filter equipment. AHRI 680 is intended to provide guidance of the industry, including manufacturers, engineers, installers, contractors and users of residential air filters. AHRI 680 does not apply to "[portable] appliances which include Air Filter Equipment in combination with fans, coils, dampers, etc., but can be applied to the Air Filter Equipment as used therein" [58].

Section 5 of AHRI 680 provides the testing requirements of residential air filters and states

"5.1 *Test Apparatus.* The test apparatus requirements and qualification shall be per ANSI/ASHRAE Standard 52.2 or Appendix E.
5.2 *Test Materials*
5.2.1 *Test Aerosol.* The Test Aerosol shall be solid-phase potassium chloride (KCl) per ANSI/ASHRAE Standard 52.2.
5.2.2 *Loading Dust.* The Loading Dust shall contain no powdered carbon. Other details of the Loading Dust shall be per ANSI/ASHRAE Standard 52.2" [58].

The following discussion outlines the findings of the types of penetration testing aerosols to determine if oil-based aerosols are required or if there is allowance for the use of alternate, approved aerosols.

Selection of Appropriate Filtration and/or Purification Mechanism

Understanding the environment, the associated contaminants, and that it is well documented that air cleaning devices and filtration is a significant contributor to improving indoor microenvironment air quality, the identification of the appropriate filtration is necessary [8, 11, 18, 24, 33, 59].

Figure 3 is provided as a mechanism for the selection of the appropriate air filtration needed as a function of particle size and also shows the capture ranges for several different types of separation equipment. Particles in air suspension will range downwards from 20 to 100 µm. Particles down to 20 µm can be visible to the naked eye, while on down to 0.1–0.2 µm they can be observed with a conventional microscope.

The major problem particles that are viruses are smaller than this, and so that much more difficult to remove. Typically, some 90% by weight of all airborne particulate impurities range from 0.1 to 10 µm in size, although this range and the actual concentration of solids will vary markedly, particulate suspension is dependent upon the

immediately local environment and air movement activity. If the air is in motion, then quite large particles could be held in suspension, particularly if the flow is turbulent. As such, 10 µm particles will be held up by quite gentle air movements, while velocities of 0.3 m/s in a vertical direction will keep 100 µm particles suspended [34].

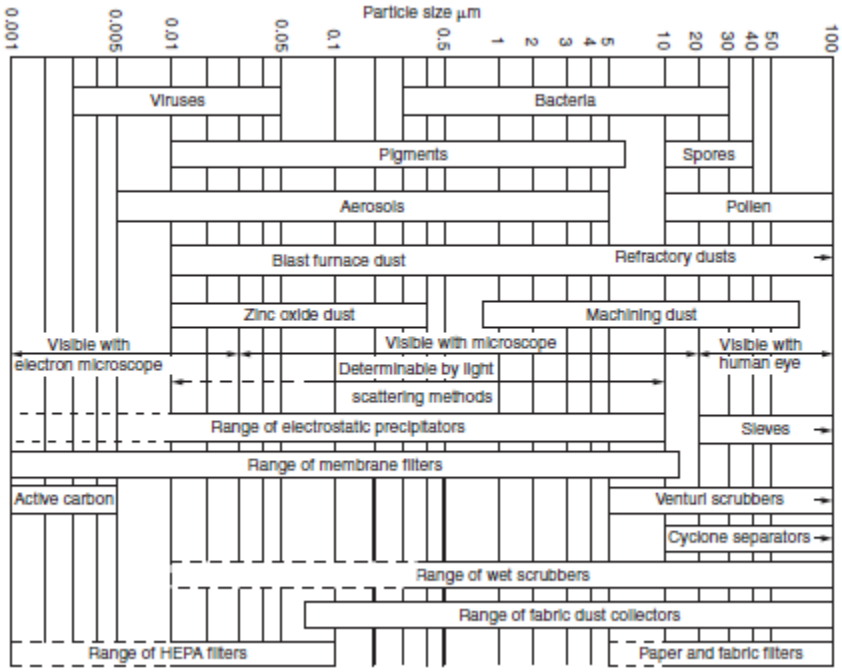

Figure 3: Contaminant size and associated required filtration [34]

The recommended practices for HEPA filter construction, performance, labeling, and certification are maintained by the Institute of Environmental Sciences and Technology (IEST) where the performance requirements are included in:

- IEST-RP-CC021 "Testing HEPA and ULPA Media, which governs requirements for the filter media
- IEST-RP-CC001.6 "HEPA and ULPA Filters", which governs overall filter construction and labelling requirements [1]
- IEST-RP-CC034 "HEPA and ULPA Filter Leak Tests, which governs HEPA and ULPA filter penetration (leakage) tests

IEST-RP-CC001.6 cites EN 1822 and ISO 29463 as normative standards the IEST is based upon. ISO 29463 (all parts) is derived from EN 1822 (all parts) and contains requirements, fundamental principles of testing and the marking for, high-efficiency particulate air filters with efficiencies from 95% to 99,999 995% that can be used for classifying filters in general or for specific use by agreement between users and suppliers [60].

ISO 29463 is recognized as the consensus standard that establishes a procedure for the determination of the efficiency of all filters on the basis of a particle counting method using a liquid (or alternatively a solid) test aerosol, and allows a standardized classification of these filters in terms of their efficiency, both local and overall efficiency, which actually covers most needs of different applications [60].

ISO 29463 defines type Group H: HEPA filters (high-efficiency particle air filter) are those filters that are "individually tested and their efficiency is determined at MPPS in accordance with ISO 29463-5. The filter is leak tested in accordance with ISO 29463-4, where, in addition to the reference leak scan method, four alternate methods for leak testing are allowed. Alternate norms used for leak testing should be clearly identified on the

filter and certifications" [60]. Certified HEPA H13 filters are credited for performance that pass up 0.05% of 0.1-micron particles per liter of air.

Table 5 provides detailed information about the permissible test methods in accordance with ISO 29463 (all parts) for each filter group and class of filters.

Table 5: ISO 29463-1 Overview of classification and test methods

Filter Class (number) Filter Group (letter)	Limit for overall value[a]		Limit for local value[a,b]		Test procedures							
	Efficiency (%)	Penetration (%)	Efficiency (%)	Penetration (%)	Overall efficiency test		Local efficiency test = Leak test[b]					
ISO 15 E	≥95	≤5	—	—	X[c]	X[c]	Filters of Group E cannot and must not be leak tested for classification purposes					
ISO 20 E	≥99	≤1	—	—	X[c]	X[c]						
ISO 25 E	≥99,5	≤0,5	—	—	X[c]	X[c]						
ISO 30 E	≥99,90	≤0,1	—	—	X[c]	X[c]						
ISO 35 H	≥99,95	≤0,05	≥99,75	≤0,25	X[d]	X[d]	X	X	X	X[e]	X	X
ISO 40 H	≥99,99	≤0,01	≥99,95	≤0,05	X[d]	X[d]	X	X	X	X[e]		
ISO 45 H	≥99,995	≤0,005	≥99,975	≤0,025	X[d]	X[d]	X	X	X	X[e]		
ISO 50 U	≥99,999	≤0,001	≥99,995	≤0,005	X[d]	X[d]	X			X[e]		
ISO 55 U	≥99,999 5	≤0,000 5	≥99,997 5	≤0,002 5	X[d]	X[d]	X			X[e]		
ISO 60 U	≥99,999 9	≤0,000 1	≥99,999 5	≤0,000 5	X[d]	X[d]	X			X[e]		
ISO 65 U	≥99,999 95	≤0,000 05	≥99,999 75	≤0,000 25	X[d]	X[d]	X			X[e]		
ISO 70 U	≥99,999 99	≤0,000 01	≥99,999 9	≤0,000 1	X[d]	X[d]	X			X[e]		
ISO 75 U	≥99,999 995	≤0,000 005	≥99,999 9	≤0,000 1	X[d]	X[d]	X			X[e]		
[a] See also Tables 1 and 2. [b] Local penetration values lower than those given in Tables 1 and 2 may be agreed upon between the supplier and customer. [c] Statistical efficiency test method may be applied per ISO 29463-5:2011, 4.2. [d] Efficiency test of each individual filter applies per ISO 29463-5:2011, Clause 8. [e] Comment in the test protocol and classification shall be made that filter is tested per ISO 29463-4:2011, Annex E.					ISO 29463-4, Test with movable probe	ISO 29463-5, Test with static probe	ISO 29463-4, Scan test (reference) Annex C	ISO 29463-4, Oil tread leak test Annex A	ISO 29463-4, Photometer scan test Annex B	ISO 29463-4, PSL leak test Annex E	ISO 29463-4, 0,3 µm leak test Annex F	ISO 29463-4, Photometer overall test Annex G

Conclusion: Portable Air Purification System HEPA Filter Entrainment of Airborne Pathogens

The entrainment of airborne pathogens is well documented and recommended as supplemental equipment for personal protective equipment in certain circumstances and applications [38, 61-75].

As measured by Liu et al., the peak concentration of pathogen aerosols appears in two distinct size ranges, one in the submicron region with aerodynamic diameter dominant between 0.25 and 1.0 µm, and the other peak in super-micron region with diameter larger than 2.5 µm. Such aerosols just fall in the size range that can be effectively removed by air purifiers as identified by Sutherland [34]. Commercially available air purifiers with certified high-efficiency particulate air filters (HEPA) for particles filtration that have been tested and certified in accordance with IEST, EN, and ISO standards may be sufficient to remove such virus-laden aerosols [70].

This research has demonstrated the efficiencies of certified HEPA are more than 95% for aerosols of diameter between 0.25 and 1.0 µm and nearly 100% for those with diameter larger than 2.5 µm can be readily entrained. However, particle entrainment is not the determining factor when selecting air purification systems. When selecting an appropriate air purification system, the consumer must also consider Clean Air Delivery Rate (CADR).

Clean Air Delivery Rate (CADR) is a performance metric that is a function of flow rate in cubic feet per minute (CFM) of air that has had all the particles of a given size distribution removed. The CADR is the fraction of particles (of a particular size distribution) that have been removed from the air, multiplied by the air flow rate (in CFM) through a given air purification system. The CADR ratings were developed by Association of Home Appliance

Manufacturers (AHAM) and are measured according to a procedure specified by ANSI/AHAM AC-1 [76]. The CADR ratings are recognized by retailers, manufacturers, standards organizations, and the US Environmental Protection Agency (EPA).

As part of the National Center for Biotechnology Information (NCBI), Zhao et al. specifically notes that "portable, affordable, and effective air purifiers have the potential to reduce the exposure of healthcare workers to virus-laden aerosols and serve as a useful supplement to other protective procedures. Moreover, for COVID-19 patients, or suspected cases, who are being quarantined at home, using air purifiers can also reduce the exposure of those in the same households to the virus-laden aerosols, thus reducing the risk of household infection" [70, 77]. The fact that the HEPA-filtration system has now been proven to be capable of reducing aerosol transmission of airborne pathogens in studies involving the use of both natural and artificial aerosols suggests that this method, despite its cost, may hold promise for reducing this risk in the field [61].

Additionally, other studies involving portable HEPA-filtration units have empirically shown significant reduction of environmental contamination due to airborne pathogens within microenvironments and is proving to be a useful addition to existing infection control measures [62]. Identified studies have shown that after the installation of high-efficiency particulate air (HEPA) as an infection control measure, there is a noted reduction in contagion due to airborne pathogens [66, 67].

Studies have shown where supplemental protective environment (PE) rooms in microenvironments the portable air purification systems are required the most stringent minimum filtration efficiency. These studies demonstrate the minimum efficiency reporting value (MERV) of 7 (MERV-7) or greater is required as a first filter before heating and cooling equipment, and a second high-efficiency particulate air (HEPA) filter is placed downstream of cooling coils and fans. HEPA filters are rated to remove at least 99.97% of particles at 0.3 µm in size, representing the most penetrating particle size [68].

In comparison, most residential and commercial buildings utilize MERV-5 to MERV-11, whereas in critical health care settings, MERV-13 or higher and HEPA filters are used. Certified MERV-13 filters have the potential to remove microbes, airborne pathogens, and other particles ranging from 0.3 to 10.0 µm. Most viruses, including CoVs, range from 0.004 to 1.0µm (52). However, viruses are rarely observed as individual particles, but instead are expelled from the body already combined with water, proteins, salts, and other components as large droplets and aerosols. Studies of the SARS-CoV-2 have observed aerosolized particles in a spectrum of sizes, including 0.25 to 0.5 µm (96), necessitating high efficiency filtration techniques to reduce the transmission potential of pathogens such as SARSCoV- 2. HEPA filters have been demonstrated to reduce virus transmission in simulated settings. However, it is important to note that leaking around the edges of the certified HEPA filtration systems in hospitals have been a contributing factor of the failure of filtering systems to eliminate pathogens from the shared air environment [68][69]. Given that coronaviruses are approximately 0.125 mm (125 nm) in diameter and that a very high proportion of particles (up to 100%) in this size range are captured by high-efficiency particulate air (HEPA) filters, it is reasonable to assume that placing a portable HEPA filtration system with a high frequency of air changes rapidly reduces the viral load within the microenvironments (e.g., operating rooms) without increasing the risk of disseminating the virus [70][71][72][73].

Therefore, this research of the published peer-reviewed literature has identified analysis where the use of a certified HEPA (high efficiency particulate air) filter in microenvironments is believed to assist in reducing the risk of transmission of infectious diseases through removing the particles or large droplets to which pathogens may be attached. This premise was substantiated through clinical studies where portable HEPA filter were used to increase the effective airflow rate of the general ward to the standard of an isolation ward for emerging infection

diseases. In this research pertaining to the potential capture of airborne pathogens by portable certified HEPA filtration systems, one specific study stands out. Qian et al. performed a study where full-scale experiments utilized a hospital ward with a dimension of 6.7 m × 6 m × 2.7 m and 6 beds to test hypotheses of the use for a portable HEPA filter and its ability to lessen the transmission of airborne pathogens. "The removal efficiency for different size particles was measured at different locations. The influence of the portable HEPA air cleaner on the airflow pattern was also studied through smoke visualization and computational fluid dynamics (CFD) simulations. Results show that the HEPA filter can effectively decrease the particle concentration level. The effective air change rate achieved by the HEPA filter (for particle removal only) is from 2.7 to 5.6 ACH in the [hospital] ward. The strong supply air jet from the portable HEPA filter interacted with the room airflow pattern and became dominate, introducing global airflow mixing in the room. Background noise levels were also measured and noise level in the room increased when the maximum airflow of the filter was used"[74].

The cited publications in this literature review indicate that protection against the transmission of airborne infection is increased by maximizing absolute ventilation per occupant, which may be achieved by increasing the number of ACH or by increasing the room volume per occupant for a given rate of air exchange. Dilutional ventilation with fresh air becomes critical for airborne infection control whenever infectious and susceptible people share air space without the use of particulate respirators, such as in waiting rooms, outpatient clinics, emergency departments, shared wards, and investigation suites. These spaces are often ventilated at levels well below those recommended for the control of pathogen transmission [38, 75].

It is important to note that whenever air purifiers are used, filters should be collected and disposed as medical waste or disinfected thoroughly to prevent secondary contamination. As there is still lack of proper guidance of handling the filters for such an application, the frequency to replace or clean the filters may should be higher than that for ordinary use. Furthermore, the air purifiers with disinfection capability may be more effective for combating the virus and could be considered for use if necessary. Such air purifiers would cost more and consume more energy, but this is perhaps of a less concern under the current pandemic situation. Finally, we should be aware that the indoor air purifiers should be used as a supplementary and precautionary measure after other more significant measures have been taken, such as local source control that includes local pollutants exhaust, filtration, removal and disinfection, as well as the frequent

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