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Medical Face Mask Filtration Testing: A proposal for a simplified and expedient method for the Evaluation of Functional Filtration Efficiency (FFE)

INTRODUCTION

There are US and European standards for measuring the bacterial and viral removal efficiency of surgical masks and their required fabrication materials. These standards were established in less turbulent times, and these methods are described in ASTM documents F2100, F2299 and F2021, among others (e.g. NIOSH and OSHA). Other standards and reports exist that cover this requirement in other jurisdictions, for instance, British Standards EN 13274-7:2019 and EN 14683.

The current COVID-19 pandemic is forcing many of us to seek alternative materials that will allow the self-fabrication of masks and filter systems. We are being asked by others, agencies and colleagues to provide advice on these issues. Many of us are unfamiliar with the methods or the equipment that can be used to address these questions. For that reason, we are making this post.

The ASTM document cited above, F2299, uses Polystyrene Latex (PSL) spheres in sizes between 0.1 and 5 microns. After being made airborne, they are delivered to the filter material. Concentrations of particles before and after the filter are used to define filtration efficiency. In addition to technical elements of the method *per se*, such as charge neutralization, an optical particle counter is used to measure the number of particles removed and then, to allow computation of filtration efficiency.

The second ASTM document cited above, F2021, calls for the use of a Staphylococcus Aureus inoculum in peptone water solution along with a Collison nebulizer followed by a 6 stage Anderson Bio-sampler, one that is loaded with petri dishes and agar for bacterial cultures. Thus, it is a bioassay that cultures the bacterial cells that have been collected on multiple stages, name differing sized partitions and then deposited on o agar-filled petri dishes. The Anderson Bio-sampler (for instance, one made and sold by Tisch Environmental, Cleves OH) yields a 6-part particle size distribution of the cultivable bacteria. One, three and six-stage samplers are currently supplied by Tisch Environmental (in manufacturing but currently unavailable). A single-stage device, BioStage, is offered by SKC Inc.

The BS EN 13274-7:2019 takes an alternate approach. It employs a sprayer that makes aerosols of Sodium Chloride (NaCl) or Paraffin Oil. In the case of NaCl detection, it uses a Sodium flame photometer after the filter as the aerosol detector for post-filtration air volumes. A second device before the filter is an option. In the case of the oil aerosol, a scattered light aerosol detector (Optical Particle Counter, OPC) is specified for pre- and post-measurement.

In contrast to these recognized but technically challenging methods requiring specialized expertise, expensive and hard to find equipment, as outlined above, we might propose a consolidated but alternative approach that is derived and adapted from these standard methods. We intend to define a Functional Filtration Efficiency (FFE), which can be used as a way to evaluate unknown materials having an uncertain filtration capability. The method relies on comparison between known and unknown and may be a desirable method for use during the pandemic.

If one can obtain certified masks or samples of certified filter media, e.g. N95 or N99, then we propose to craft a testing system that allows a comparison between two or more filtration media, one or more known product(s) and others, although unknown, that may be compared to standards.

OUR PROPOSAL

We propose to define a consolidated test method that, to the extent possible, uses easily obtained materials, while it is still robust enough to be consistent with the regulatory, health and safety requirements. Our justification for offering this FFE procedure is that the methods cited above are complicated, expensive and require specialized equipment. ASTM F2299 calls for an optical particle counter with a charge neutralizing device (radioactive, X-Ray or Corona discharge). ASTM F2201 uses a bacterial culture that requires time, technical expertise and specialized microbiological counting equipment. The BS EN standard 13274-7:2019 likewise uses specific elements that may not be available in many labs in the COVID-19 world.

MATERIALS AND METHODS

Spray Device

The aerosol will be generated by a pneumatic sprayer, either an atomizer or a nebulizer. An atomizer has no secondary impact surface, while a nebulizer requires that sprayed particles impact and shatter on a secondary surface. CH Technologies and other manufacturers supply devices in both of these categories. Other available devices of comparable functionality but unknown availability might be employed. In the case of CHT products, the sprayers could be one of the following: 1, 3 or 6 jet Collison or a 1, 4 or 8 jet Blaustein Atomizer (BLAM) or the single jet BioAerosol Generating Nebulizer (BANG).

The Collison is a well-defined pneumatic sprayer that was developed in the 1970s by Dr. Kenneth May (https://doi.org/10.1016/0021-8502(73)90006-2); it was offered for sale by BGI of Waltham, MA with ownership transferred to CH Technologies after BGI was purchased by Mesa Labs. It is specified by ASTM 2299. It was employed by Eninger et al. (2008) in DOI:10.1093/annhyg/men019 among other investigators.

The aerosol-generating devices will be operated with pneumatic pressure from a clean, dry compressed air source. As a starting value, we propose 20 PSIG and this pressure will set the flow rate through the device to be used. Various methods might be used to measure the airflow that results. One tool that may be readily available is the Dwyer Plastic Rotameter. As a starting point, the three jet Collison flow value might be set to 6 litres per minute (lpm).

Spray Fluid

A readily available liquid should be used. Normal Saline (0.9% NaCl in Distilled or Deionized water) is one example. Di-2-Ethylhexyl Sebacate (DEHS) is also identified in some publications, but, one possible choice might be Pedialyte, a rehydration liquid readily found in pharmacies. It is a fluid that contains glucose plus Sodium and Potassium salts. When used as purchased or after dilution to a working concentration (1 qs 10 or 1 qs 100 and values between), it can be used to form an aerosol of various concentrations that will consist of particles less than 2 microns in diameter when dried. It can be readily prepared by the cited pneumatic sprayers and subsequent mixing with additional air with time allowed for drying.

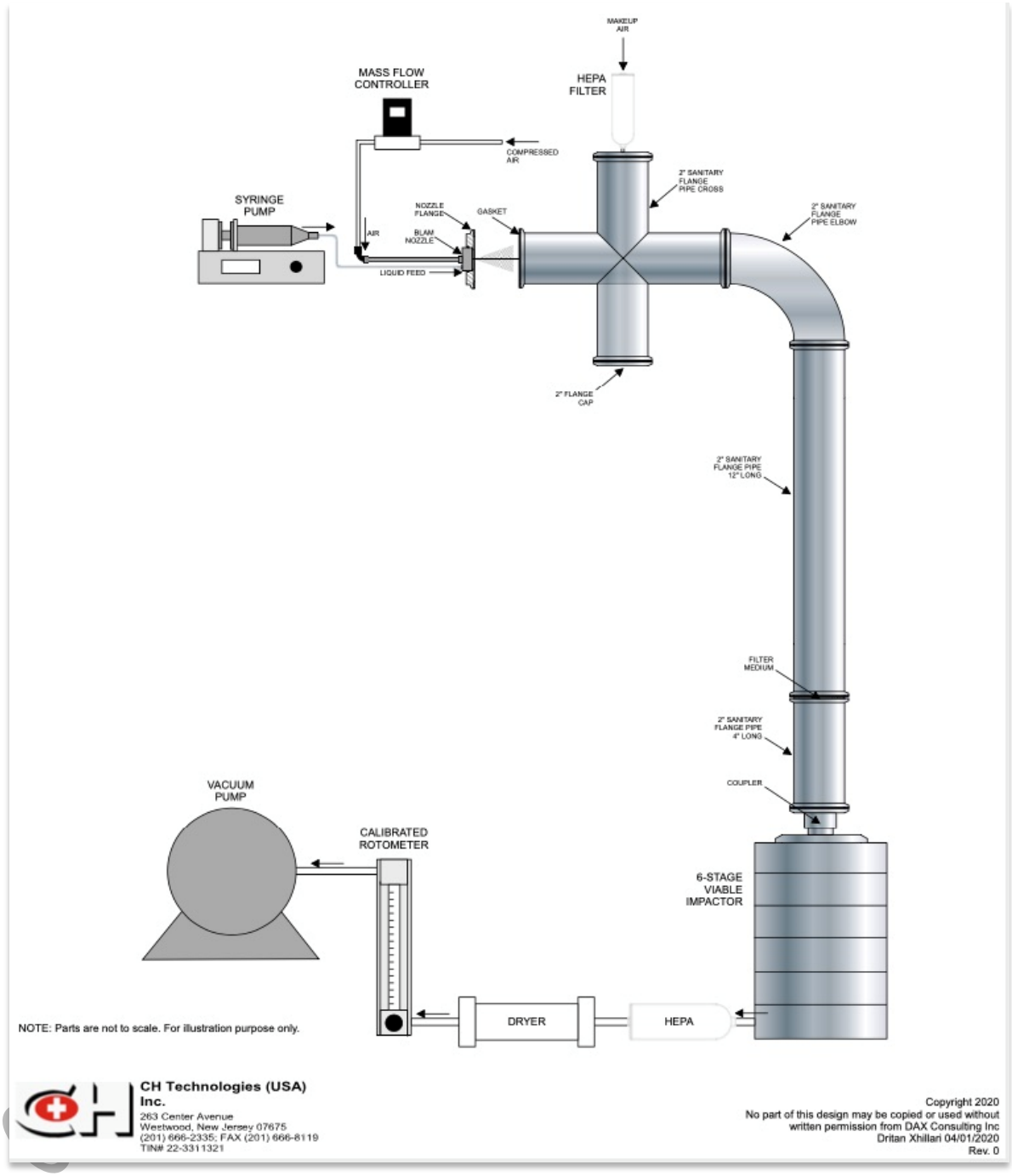
Step one, using undiluted Pedialyte, the spray device can be set at 6 lpm. The 5/8" outlet from the aerosol generator might be diluted with clean, dry air, 30 liters, from a compressor that is suitable for the purpose. In our case, we use a purpose crafted Werther compressor with internal filtration and regenerative drying. The compressed breathable air might also suffice, if available.

No charge neutralization is proposed at this time to maintain the simplicity of the proposed method. Subsequent investigations might use this technology if time, standards or results make it required.

Dilution and Mixing

The 5/8" Collison outlet is connected to a variable diluter that is configured and designed for this purpose; one such device, namely a 10 to 1 Tee, is available from CH Technologies. A sidearm with suitable fitting is connected to the Werther air source. This flow value initially set to 30 lpm, is slightly more than one CFM. The diluted aerosol is directed to an aerosol plenum that is more than 10 inlet diameters in length. In this case, a value of 6 inches long may suffice for mixing and drying.

A stainless-steel tube that is grounded is specified for charge neutrality. A 2-inch diameter and 6 to 12-inch tube length should be sufficient to allow for drying and diffusional mixing.



Setup 1: Alternative to ASTM F2101: Tests with Staphylococcus Aureus

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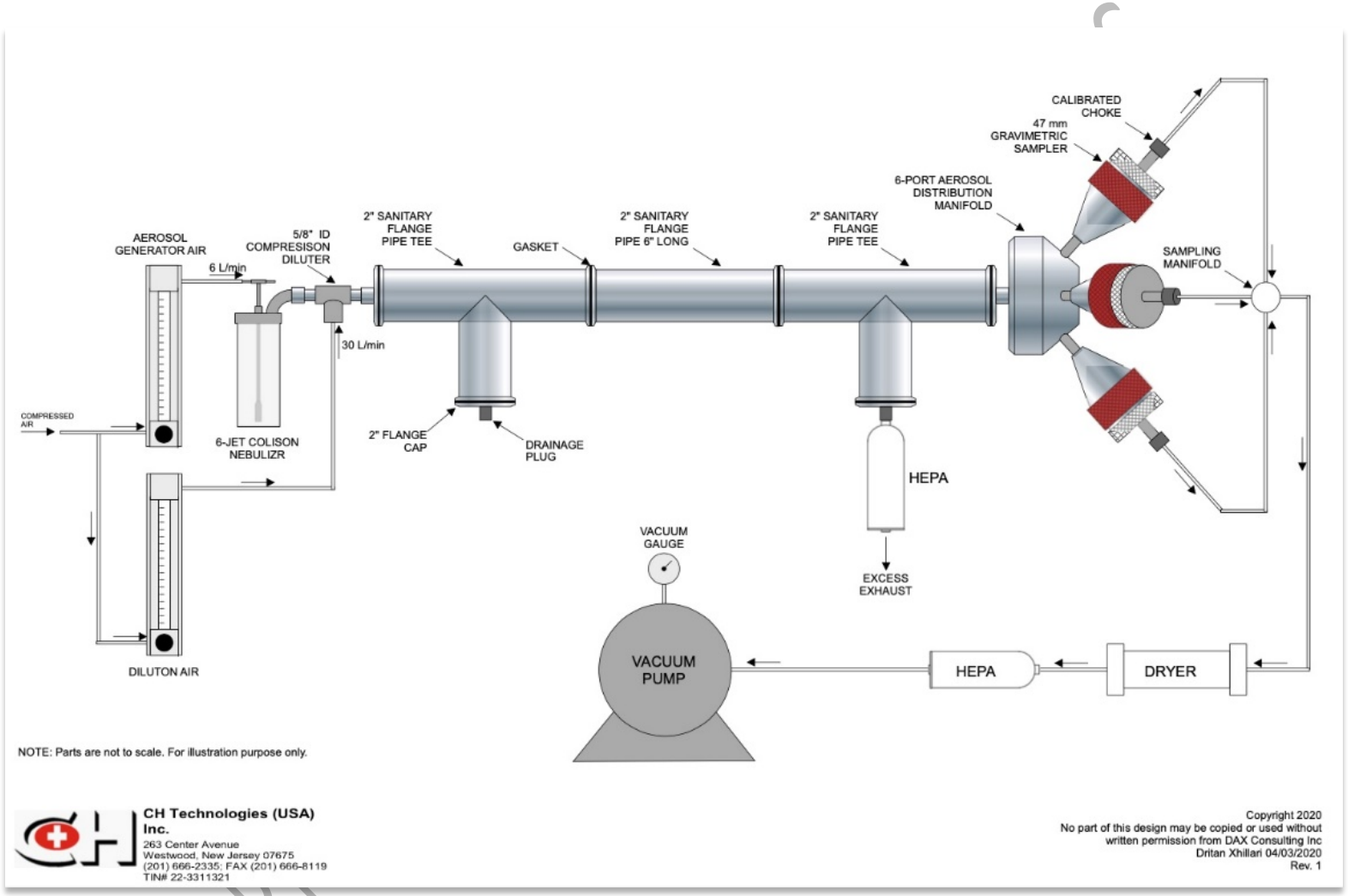

Setup 2: Alternative to ASTM 2299: Tests with Salts or Pedialyte

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Size Selection (Optional)

Cyclonic filtration allows for the removal of particles of a specific size and then to enrich fractions smaller than the cut-point, which are more likely to be more penetrating into the lung. Respirable particles are less than 4 microns, while particles of 0.3 microns are cited as most penetrating through masks and filter media. This penetration is reported to depend on the face velocity and flow through the filter.

To enrich the smaller particle size fraction continuously, we propose to employ a BGI supplied cyclone that can be provided by Mesa Labs, Butler, NJ. The design and characteristics remain to be defined. Still, one model that may be satisfactory is the Sharp Cut Cyclone 3.445 (SCC 3.445) operated at 1 CFM (28.3 lpm), an elevated flow rate to yield a D50 cut point of less than 1 micron.

The device proposed yields a reasonable amount of aerosol of less than 1 micron of salts and glucose at about 37 to 40 lpm. About 1.5 CFM will be available for sampling.

Sampling

A purpose-built 3 to 6 port vacuum-manifold with suitable fittings for three or more 47 mm CHT filter holders is proposed. The inlet of the filter can be inserted into a vessel that contains the outlet of the cyclone that delivers the separated aerosol. As the system is open, the controlled outlet will offer sufficient aerosol flow that the three samplers can collect the aerosol without the need to adjust pressures.

Each of the CHT filter holders are operating at an inlet flow of 10 liters per minute (lpm) using a flow controlling choke on each. A vacuum pump creates suction at less than one-half atmosphere. Fiberglass filters are initially suggested for use, but polymeric filter media might also be employed.

The system is operated for 10 minutes to stabilize flows and concentrations before the filter samplers are inserted or introduced into the air stream.

Samples (Setup 2)

A steel disk cutter is used to make 47 mm disks. Known efficiency filtration media will be compared to No Filtration or to an unknown filtration material. In this way, a variety of other materials may be evaluated.

A FILTER DISK ONLY (control)

B FILTER DISK installed in holder with no filter test material in front of it (100% condition)

C FILTER DISK media PLUS 47 mm cut circle of known or N95 media laid in front of the filter disk medium (this is this N95 comparison)

D FILTER DISK media plus a 47 mm cut circle of unknown filter efficiency.

Suggested time and flow: The three filters samplers are operated for 15 minutes at a flow rate of 10 liters per minute. After the chosen operational time, the filter disks are opened, the internal disks carefully separated. The removed collection disks (3 tested and one control) from the three holders are inserted into 50 ml plastic centrifuge tubes with caps. Each tube (A, B, C and D) plus the control is treated with 25 ml of distilled water. The fifth tube contains only 25 ml of distilled water. The tubes are vigorously mixed and allowed to stand for 30 minutes.

Measurement Options

1. ***Measure electrical conductivity*** following collection of Sodium Chloride aerosol onto a collecting filter. Verify that filter used, fiberglass Cambridge type filter or Teflon filter collects 100% of the sampled aerosol. The collecting filters are placed into suitable test tubes with a measured volume of distilled or deionized water. The salt is allowed to extract into the aqueous phase. Rapid mixing should be used. The samples are compared as to their conductivity for the 100% case (no filter media present in front of the collecting filter), the zero case or control condition where the collecting filter not exposed to any aerosol (control for conductivity of filter) versus the case of the unknown filter media placed in front of the collecting media. ***This method is currently under development.*** An electrical conductivity meter, e.g. ttps://www.mt.com/us/en/home/library/operating-instructions/process-analytics/InPro-7100i.html.

2. ***Measure glucose concentration*** – There is a method that can use standard glucose meters to estimate glucose in water solutions from collected glucose on filters.

3. ***Use an optical particle counter*** to determine the number of particles in the case of no filter media present versus a known filter media being present. This value is then compared to the unknown filter media.

Disclaimer

*The views, thoughts, artwork, schematic representation of proposed setup and opinions expressed in the post belong solely to the CH Technologies (USA) Inc. Researchers can use the proposed method for further research, testing and validation. CH Technologies (USA) Inc. takes "**no responsibility**" from being held responsible for or held liable for things like damages that arise from using this proposed method. We do not make any warranties about the completeness, reliability and accuracy of this information. CH Technologies cannot be held responsible if the proposed method does not work for someone.*