EasyOne Filter – Filter Efficiency

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1. Introduction

ndd EasyOne spirometers are based on ultrasound flow measurement. They make use of disposable breathing mouthpieces to channel the air flow that is measured by the ultrasonic sensor. Exhaled air carries particles that potentially contain pathogens, i.e., bacteria or viruses, which might contaminate the sensor and the testing site. ndd's disposable breathing mouthpieces and the EasyOne Filters address both aspects. They separate the sensor from the exhaled air and prevent pathogens from entering the testing site.

2. Background

Filtration is a process in which particles in the air are retained by a filtering medium. Filtration consists of several mechanisms that operate simultaneously. Figure 1 shows how these mechanisms (Brownian motion, interception, and impactation) interact and how the efficiency of filtration depends on the particle diameter [4]. The term MPPS (most penetrating particle size) denotes the particle diameter where the specific filter shows the lowest efficiency, i.e., particles with diameters above and below MPPS are filtered with higher efficiency.

Figure 1 additionally highlights the particle diameters used in the different filter tests. Since the NaCl penetration test runs with particles with a diameter close to the MPPS, these results represent a worst-case scenario. The other two tests performed at Nelson Labs and UK Health Security Agency (UK-HSA) use droplets that carry bacteria for Bacterial Filter Efficiency (BFE) testing and phages for Viral Filter Efficiency (VFE) testing. The aerodynamic diameter of the droplets is more important for the filtration efficiency than the size of the organisms they carry.

In addition, the mechanisms of filtration also depend on flow velocity.

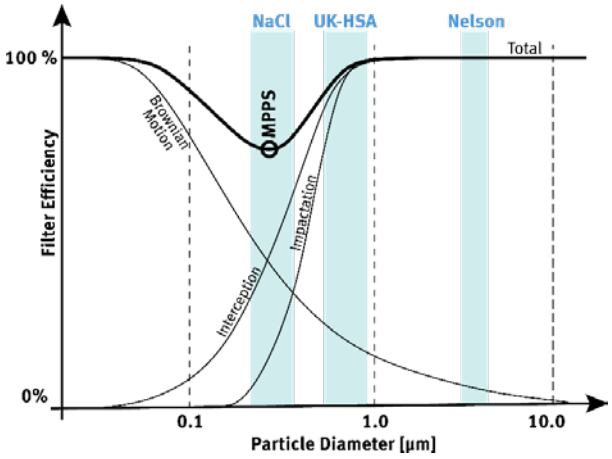

Figure 1: Filter efficiency versus particle diameter

3. Filter Efficiency Tests

Airborne aerosol particles found in exhaled air cover the entire size range from less than 1 µm up to more than 4 µm [3]. To cover a large range of particle sizes, ndd has selected different tests that include three particle diameters, three flow velocities, and four different challenge organisms.

- BFE and VFE tests with the EasyOne Filter were performed at Nelson Labs using an increased challenge level, a flow rate of 30 L/min, a suspension (droplet size ~3 µm) of *Staphylococcus aureus* (size ~1.0 µm) [1], and a suspension of bacteriophage ϕ X174 (size ~0.025 µm) [2].
- At the UK Health Security Agency (UK-HSA, formerly Public Health England) BFE and VFE tests at a flow rate of 750 L/min were performed using a suspension (droplet size <1 µm) of *Brev. diminuta* (size ~0.8 µm) and a suspension of *MS-2 Coliphage* (size ~0.025 µm).
- NaCl penetration tests (particle size ~0.3 µm) were performed at a flow rate of 30 and 90 L/min.

The following table shows the main results of these tests:

Nelson Labs, 30 L/min (increased challenge level)	**Test performed**	**Efficiency one-way** (average of 3)
BFE, *Staphylococcus aureus*, size ~1.0 µm [1]	10 2021	99.999427%
VFE, ϕ *X*174, size ~0.025 µm [2]	10 2021	99.989967%
UK Health Security Agency, 750 L/min	**Test performed**	**Efficiency one-way** (average of 3)
BFE, *Brev. Diminuta*, size ~0.8 µm	03 2022	99.699%
VFE, *MS-2 Coliphage*,size ~0.025 µm	03 2022	99.571%
NaCl penetration test, (TSI 8130, ~0.3 Micron)	**Test perfomre**	**Efficiency one-way** (average of 10)
Flow rate 30 L/min	01 2022	98.56%
Flow rate 90 L/min	01 2022	95.14%

4. Conclusion

The EasyOne Filter was tested at several facilities using multiple standardized methods, flow speeds, and particle diameters. These tests show that the filter is efficient with the most challenging organisms. The diameter of a SARS-COV-2 virus, for example, ranges from 0.06 to 0.14 µm, and its carrier particles range in size from 0.25 to 4 µm (aerosols) but could be as large as 10 µm [5]. The tests performed show that the EasyOne Filter has a high filter efficiency for these particle sizes.

Based on the evidence of our tests, it can be concluded that the EasyOne Filter protects patients and staff well from airborne pathogens. Furthermore, ndd's single-patient-use breathing mouthpieces prevent the risk of cross-contamination (to consult test-based evidence, please see our Application Note *Cross-Contamination Assessment* available on our website at www.nddmed.com).

5. References

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