Air*Life*™ 001853 high-efficiency respiratory filter

Technical bulletin of independent and internal lab test results

Cross contamination is a major concern in both the ICU and operating room. Filtration devices help to defend against microbial infections, such as TB, SARS, Pneumonia and other serious illnesses, depending on the quality of filter media. The particle size and quantity parameters determine how challenging the filtration efficiency test is for the filter media. The tests ensure that specific sizes of particles cannot penetrate the media. The particle size is commonly referred to as microns (e.g., 0.3µm) within this study.

Purpose

The purpose of this technical bulletin is to provide a comparison summary of the in vitro performance characteristics of our new Air*Life*™ high-efficiency filter (001853) to an intersurgical filter (ISG1944). An independent lab, Nelson Laboratories of Salt Lake City, Utah, conducted the filtration efficiency testing. Multiple samples were evaluated under the following three tests:

- NaCl filtration efficiency based on ISO 23328-1
- Bacterial filtration efficiency
- Viral filtration efficiency

CareFusion internally tested and validated the following tests based on industry standards and protocols:

- Flow resistance based on ISO 9360-1: 2000
- Water retention

CareFusion

NaCl filtration efficiency testing: ISO 23328-1

Overview:

This testing is currently the only international standard for measuring the efficiency of breathing system filters. Like the NIOSH standard, it uses a charge-neutral sodium chloride aerosol of the most challenging particle size (~0.3µm). As a result, efficiency values from this test show less "nines" than the more common BFE/VFE tests.

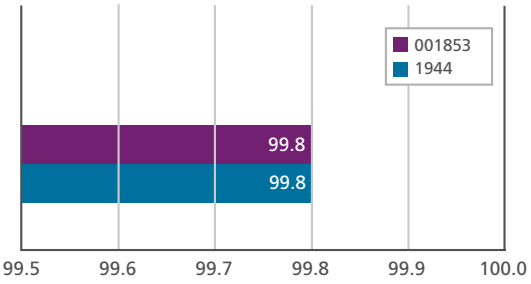
Nelson Lab test method:

The filter tester used in this procedure was a TSI CERTITEST Model 8130 Automated Filter Tester capable of measuring efficiencies up to 99.999%. The filter tester produced a particle size distribution with a count median diameter of 0.075 +/- 0.020µm and a geometric standard deviation not exceeding 1.86µm as determined with a scanning mobility particle sizer (SMPS). The salt aerosol used the most penetrating aerosol size (~0.3µm). The aerosol particles were charge-neutralized and the filter tester allowed for instantaneous (no average) penetration measurements. The filters were challenged at a flow rate of 30 L/min.

Summary of results:

- The results show the filtration efficiency of the 001853 filter to be the same as Intersurgical filter 1944 in the dry condition
- The 001853 filter shows higher filtration efficiency than Intersurgical filter 1944 post conditioning (ventilator and accelerated aging)

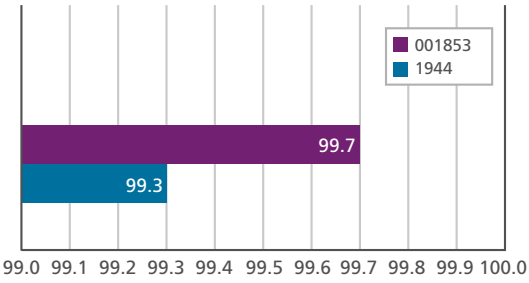
NaCl efficiency % (dry condition)



Notes:

1. **"Dry condition" refers to filters that have been removed from the packaging and undergone filtration efficiency testing.**
2. **Nelson Lab report # 415231.**
3. **n=10 for each group.**

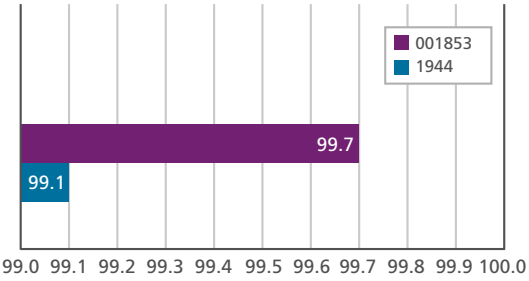
NaCl efficiency % (wet conditioning)



Notes:

1. **"Wet conditioning" means that the filtration efficiency testing was performed after the product was used on a ventilator under simulated conditions. These filters were placed on the expiratory limb of a dual-heated circuit for 24 hours (per CareFusion Protocol 07-026) and then tested for filtration efficiency.**
2. **Nelson Lab report # 384366.1.**
3. **n=4 for each group.**

NaCl efficiency % (post accelerated aging)



Notes:

1. **"Post accelerated aging" means that, prior to testing, filters were conditioned in an oven for 7 days at 60° C, 50% RH and then tested for filtration efficiency.**
2. **Nelson Lab report # 416398.**
3. **n=15 for each group.**

Bacterial filtration efficiency test (BFE) and viral filtration efficiency test (VFE) at an increased challenge level

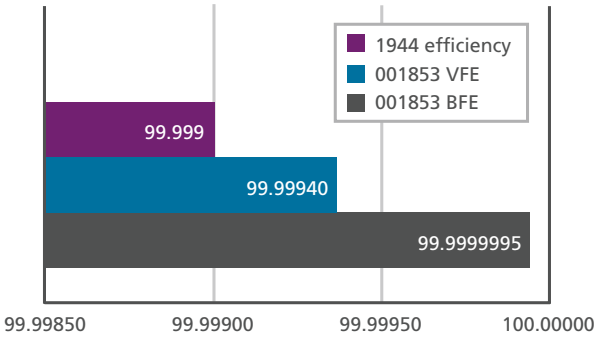
Overview:

The BFE procedure is performed to determine the filtration efficiency of various materials and filtration devices using a challenge organism of Staphylococcus aureus. The test provided a challenge level of 4.4 x 10^6 colony forming units (CFU) per test sample. This method was adapted from ASTM F2101. The mean particle size (MPS) was 3.0µm. The VFE procedure is performed to determine the filtration efficiency of various materials and filtration devices using a challenge organism of the bacteriophage ΦX174. The test provided a challenge level of 2.5 x 10^6 PFU (plaque forming units) per test sample. This method was adapted from ASTM F2101. The mean particle size (MPS) was 2.7µm.

Summary of results:

The BFE/VFE results of the 001853 filter are equal to or better than the filtration efficiency claim on Intersurgical filter 1944 product labeling.

Filtration efficiency (%)



Notes:
1. **BFE: Nelson Lab report # 363889.**
2. **VFE: Nelson Lab report # 363890.**
3. **1944: Data per product labeling.**

Flow resistance: ISO 9360-1: 2000

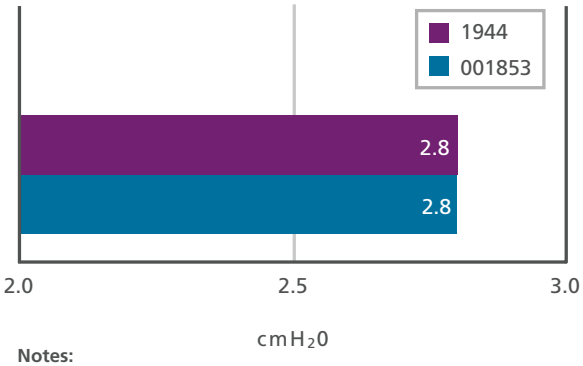
Overview:

The filter (in the unused condition) is connected to a system constructed to the above ISO standard. A flow rate of 1 L/sec is sent through the system, and the pressure drop through the filter in the expiratory direction is recorded.

Summary of results:

The two filters are comparable with respect to pressure drop.

Flow resistance @ 1 L/sec



Notes:
1. **CareFusion Project File RT-05-029 (SVR000082, attachment 4).**
2. **n=4 for each group.**

Condensation/water collection

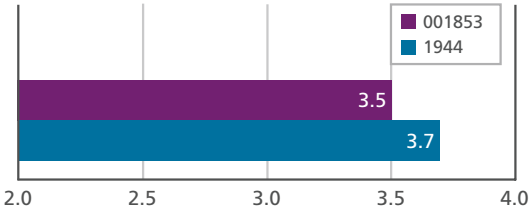
Overview:

Excessive condensation in the filter is a common reason for filter replacement. Frequent change-outs create a nuisance for the clinician. To assess this performance requirement, CareFusion conducted internal protocol RT-07-026, where the 001853 filter was tested against Intersurgical filter 1944. Filters were placed at the expiratory limb of a dual-heated circuit and run for 24 hours with a ventilator, test lung and heated humidifier. At the conclusion of this test, weight gain of the filter was measured.

Summary of results:

The two filters are comparable with respect to water collection.

Filter weight gain (Post 24 hr ventilator conditioning)



Notes:
1. CareFusion RT-07-026.
2. n=4 for each group.
3. Ventilators: PB7200.
4. Circuit: adult, dual-limb heated circuits 9066-HS7.
5. Humidifier: F&P MR 730.

Conclusions

The results conducted by Nelson Lab showed the filtration efficiency of the 001853 filter to be equivalent to or better than Intersurgical filter 1944 in the dry, wet and accelerated age test conditioning. Both filters are comparable with respect to pressure drop/flow resistance and water retention.

References

1 Thiessen RJ. Filtration of Respired Gases: Theoretical Aspects. *Respir Care Clin*, 2006; (12):183-201.

2 Demers RD. Bacterial/viral filtration: let the breather beware! *Chest*, 2001; 120(4):1377-89.

3 International Organization for Standardization. Breathing system filters for anaesthetic and respiratory use – part 1: salt test method to assess filtration performance (ISO 23328-1:2003). Geneva (Switzerland): *International Organization for Standardization*; 2003.

⚠ **WARNING**—U.S. Federal Law restricts this device to sale by or on the order of a physician.

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