

## MicroGard® Superior PFT Filter Performance...

### Introduction

Respiratory Care departments in hospitals and clinics around the world rely on the filtration technology from SensorMedics, a subsidiary of VIASYS Healthcare, Inc. The MicroGard pulmonary function filter acts as a barrier for the protection of patients, staff, and instrumentation from bacterial and viral contamination.

When you order the MicroGard filter, you receive our commitment that it has been produced using the highest quality materials, stringent manufacturing standards, and extensive quality control measures. Quality systems in VIASYS Healthcare's Respiratory Technologies division at SensorMedics' manufacturing facilities are certified to meet ISO 9001 and EN 46001 standards. Additionally, the MicroGard filter has received market approval from the Food and Drug Administration, K934272.

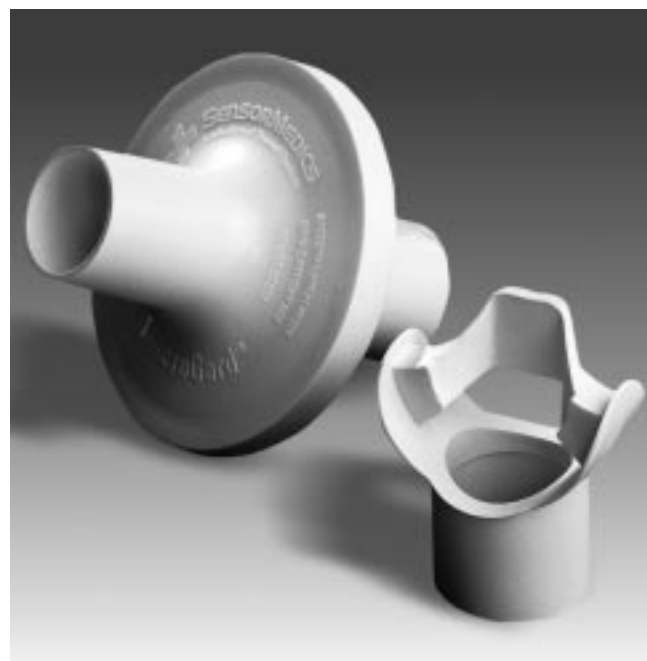


Figure 1. MicroGard Filter and FreeFlow™ Mouthpiece.

### Independent Testing

A recently performed series of scientific tests of the MicroGard filter along with filters from nine other manufacturers at Nelson Laboratories, Salt Lake City, Utah, was sponsored by VIASYS Healthcare.

Nelson Laboratories performs hundreds of bacterial removal efficiency tests every week using standardized operating procedures (SOP). The use of SOP's ensure both the manufacturer and the potential customer of reliable testing in relation to the filter's performance.



## TEST RESULTS

<i>Brand Name</i>	<i>Manufacturer</i>	<i>Bacterial Filtration Efficiency (BFE) Challenge (CFU) 2.6 x 10<sup>6</sup></i>	<i>Viral Filtration Efficiency (VFE) Challenge (PFU) 5.0 x 10<sup>6</sup></i>	<i>Delta P (TSI) (mm H<sub>2</sub>O @ 30 L/min)</i>
MicroGard®	SensorMedics Corp.	>99.99%	99.95%	1.7
Spirogard™	Marquest, Inc.	>99.99%	>99.99%	2.5
Spirobac	Mallinckrodt, Inc.	89.00%	93.10%	1.0
SureGard	RJ & VK Bird PTY., LTD	>99.99%	>99.99%	2.1
Pulmogard	CDX Corp.	99.70%	99.65%	1.4
Clear Advantage™	Creative Biomedics, Inc.	99.95%	99.90%	1.0
Collins DC-1	Collins Medical, Inc.	45.00%	57.00%	0.95
Ko Ko Moe	Pulmonary Data Service, Inc.	>99.99%	99.94%	1.1
PF30S Pro-Tec® Filter	Pall Medical	61.00%	60.00%	0.48
Bacterial/ Viral Filter (BVF)	Vitalograph® USA	>99.99%	>99.99%	2.6

The Standard Operating Procedure used represents:

- A constant flow of aerosol at a rate of 30 liters per minute, which is considered a severe challenge to the test filter.
- An aerosol particle size of approximately 3.0 microns, also considered a severe challenge to the test filter.
- Testing several filter samples to ensure the efficiency is consistent between manufactured lots of the filter media.

### BFE/VFE Efficiency

It is important to know that the viral filtration efficiency was performed using the bacteriophage virus, which, at 0.027 microns, is one of the smallest known viruses. It is considered to represent a severe challenge to

the filter media due to its diminutive size and morphology. In comparison, the HIV virus is 0.042 microns while the Hepatitis C is 0.03 microns. Bacteria such as Tuberculosis, by contrast, are much larger in size than viruses.

### Filter Media

The proprietary filter media used in the MicroGard is a patented special blend of polymers with a highly stable electrostatic charge on every individual fiber of the material. The filter media consistently achieves high efficiencies by deploying both the electrostatic charge and mechanical mechanisms to remove airborne particles. The high efficiency of the charged media allows for a more open matrix of fibers; this results in a minimal restriction to airflow.

Most filtration materials use surface loading



as the primary means of removal. With the media used in the MicroGard product, the fiber matrix results in depth loading, where particles are captured throughout the entire filter media, not just on the surface. The filter media is composed of polymer fibers that will not support the growth of mold, mildew, fungus or bacteria. This material also resists degradation over time and is able to withstand extreme temperature and humidity.

### Flow Rate

It is crucial for the clinician to be aware that the bacterial filtration efficiency (BFE) and viral filtration efficiency (VFE) are almost always directly correlated to the basis weight of the filter media, which is also correlated to the flow resistance, referred as the Delta P ( $\Delta P$ ). As the basis weight increases, the filtration efficiencies are higher and so is the Delta P. The scientific challenge therefore is to obtain the best possible BFE and VFE efficiency without jeopardizing a higher Delta P. The MicroGard Filter has achieved this delicate balance of high efficiency while maintaining low flow resistance with documented results of >99.99% (BFE), >99.95% (VFE) and  $\Delta P$  1.7 mm H<sub>2</sub>O @ 30 L/min.

### Technology Driven

VIASYS Healthcare Respiratory Technologies, a world leader in respiratory care diagnostic equipment, continually challenges its Research and Development staff to remain on the cutting edge in technology-driven advancements. The MicroGard filter represents the most advanced technology and materials available on the market today.

### Conclusion

Based upon the scientific tests results conducted by Nelson Laboratories, the MicroGard Filter proves to have the combination of greatest filtration efficiency with lowest resistance (Delta P) to airflow of any of the filters tested.

### Regulatory

- FDA 510(k) #K934272

### Optional Adapters

- P/N 42108 Rubber Coupler for Model 2450, 2130, SpiroTech
- 769204 MicroGard Filter, Box of 25
- 772505 MicroGard Filter, Box of 100
- 773892 MicroGard Plus, Box of 20
- 773893 MicroGard Plus, Box of 70
- 774572 MicroGard PFT Test Kit, Box of 50
- 773470 FreeFlow Mouthpiece, Box of 12
- Adapters available to fit all PFT devices



Figure 2. MicroGard Plus. Includes MicroGard filter and FreeFlow™ mouthpiece.



Figure 3. MicroGard PFT Test Kit. Includes MicroGard filter, nose clip, and plastic mouthpiece.



**References:**

1. Nelson Laboratories, Inc. Technical Reports Number's 187662,187663,187664,190110 (July/August 01).
2. American Thoracic Society. Single Breath Carbon Monoxide Diffusion Capacity (transfer factor). 1995 Update. Recommendations for a Standard Technique. Am J. Respir Crit Care Med Vol 152 pp 2185-2198, 1995.
3. American Thoracic Society. Standardization of Spirometry. 1994 update. Am Respir Crit Care Med Vol 152. pp 1107-1136, 1995.

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