



Cardiopulmonary Review

MICROGARD™ II



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MicroGard™ II

The use of disposable in-line filters for pulmonary function testing (PFT) has become standard practice in most facilities worldwide. Hospital acquired infections are one of the reasons why the cost of health-care is increasing. In respiratory care the use of validated pulmonary filters is an efficient measure to prevent contamination. Not only do they prevent contamination of the equipment by potential pathogen transmission via the patient's exhaled air but also patient cross contamination. Furthermore, filters protect the staff from coming in direct contact with the exhaled

air during the breathing maneuvers. With regard to the COVID-19 pandemic, both the European Respiratory Society (ERS) and the American Thoracic Society (ATS) recommend pulmonary filters as a prerequisite when performing pulmonary function tests in order to comply with the strict hygiene requirements.¹

This paper reviews the characteristics of the MicroGard™ II filter with particular regard to mandatory hygienic and technical requirements in pulmonary function testing.

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MicroGard™ IIC with disposable mouthpiece during DLCO measurement

Introduction

When using filters on pulmonary function equipment, their impact on various parameters needs to be considered to ensure correct measurement results. Above all, these include:

- filter efficiency
- airflow resistance
- effective dead space of filter
- compliance with equipment

Efficiency versus resistance

The relation between thickness and area of the filter material determines the resistance the patient is experiencing on inhalation and exhalation. The challenge is to achieve an optimal balance between the best possible filtering effect and an acceptable resistance.

Bacterial Filtration Efficiency (BFE) and Viral Filtration Efficiency (VFE) are correlated to the basis weight of

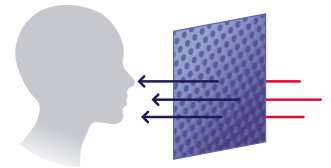
Filter resistance at various flows: MicroGard™ IIB (± 4%)			
L/s	L/min	kPa.s/l	cmH ₂ O
0.50	30	0.034	0.35
1.00	60	0.036	0.37
1.67	100	0.039	0.39
5.00	300	0.051	0.52
8.33	500	0.063	0.64
10.0	600	0.069	0.71
11.7	700	0.075	0.77
14.0	840	0.084	0.86
14.0	840	ATS¹ max. 0.150	ATS¹ max. 1.53

the filter media, which is also correlated to the flow resistance, referred as the delta P (ΔP). As the 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 causing an excessive delta P.

The MicroGard™ II filter has been designed to address this trade off, achieving a high measurement quality with an optimum performance balance.

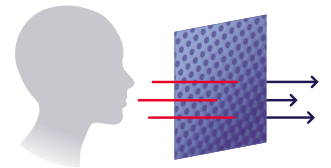
Inspiratory resistance:

<0.04 kPa/(L/s) at 1 L/s
<0.4 cmH₂O/(L/s) at 1 L/s



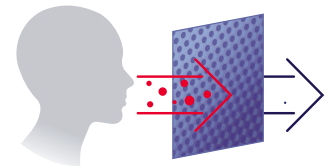
Expiratory resistance:

<0.04 kPa/(L/s) at 1 L/s
<0.4 cmH₂O/(L/s) at 1 L/s

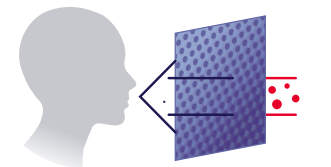


Filter efficiency against cross contamination:

viral and bacterial
> 99.999% (based on Nelson Lab test with a filter of 7 years of age)



MicroGard™ II combines a high pathogen filter efficiency with a low resistance of 0.084 kPa.s/l at an air flow of 840 l/min, which is well below the ATS recommended maximal limit of 0.150 kPa.s/l.



Dead space

The minimal dead space contribution (only 55ml's) of the MicroGard™ II filter helps Vyair Diagnostic products achieve compliance with dead space recommendations put forth by the European Respiratory Society (ERS) and the American Respiratory Society (ATS).

Compliance testing with equipment

MicroGard™ II filter is approved by the Food and Drug Administration (510 (K) K111408) and the National Medical Products Administration (NMPA) 20152082110).

Pulmonary filters are CE-certified medical devices of class IIa. In pulmonary function testing (PFT), they are used in combination with other CE-marked medical devices such as spirometers. It is mandatory for the manufacturer to demonstrate the conformity for the combination of different CE-marked medical devices.

Combination of CE-labelled medical devices

The interfaces of the individual components (medical devices) are to be examined, e. g. according to the standard EN 60601-1, and the whole system/treatment unit should be assessed based on a risk analysis, e.g. in accordance with the EN 14971 standard.

MicroGard™ II is the only filter that has gone through a full verification and validation process together with the medical equipment of Vyair PFT products it is used

on. If a device of the Vyair respiratory diagnostics line is to be combined with a filter, an optimum measurement performance can therefore only be guaranteed with MicroGard™ II. Where applicable the linearization tables for the flow sensors are corrected to generate the most accurate measurement results. This level of accuracy cannot be ensured when other non-validated filters are used instead.

Validated SentrySuite™ software corrections particularly tailored to MicroGard II:

- correction of the filter's dead space
- correction of the filter's resistance for the measurement of specific airway resistance
- BTPS (body temperature, pressure, saturated with water vapor) correction to aide in stability and minimization of drift

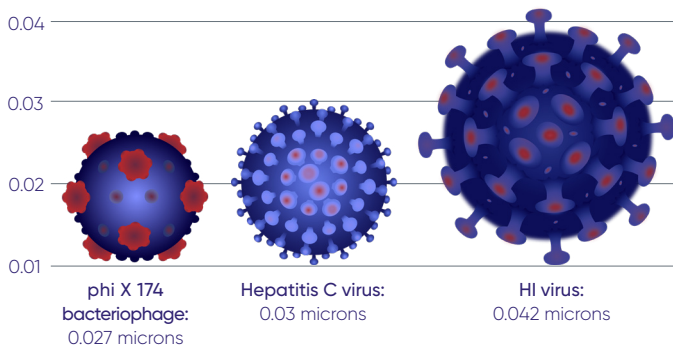
In ultrasound based PFT devices such as Vyntus™ BODY and Vyntus™ ONE, the MicroGard™ II filter is an integral part of the whole measurement system, as well as polytubes downstream of the filter which ensure a predictable flow pattern.



MicroGard™ IIC with disposable mouthpiece during body plethysmography

Efficiency testing

Nelson Laboratories (Salt Lake City/USA) performed hundreds of bacterial and viral efficiency tests using standardized operating procedures.² The viral filtration efficiency testing was performed using the bacteriophage phi X 174 which, at 0.027 microns, is used as a surrogate for viruses. It represents a significant challenge to the filter material due to its diminutive size and morphology.



Size comparison of different viruses

In comparison, the Hepatitis C virus is 0.03 microns while the HIV virus is 0.042 microns. COVID-19 is reported to have a particle size of 0.08 – 0.16 microns, significantly larger than the bacteriophages used by Nelson in the effectiveness tests. Bacteria such as *Mycobacteria tuberculosis*, by contrast, are much larger in size than viruses.

Bacterial & viral filtration efficiency at low and high flows

MicroGard™ II is the only filter that passed the bioburden test in combination with Vyaire PFT equipment regarding the accumulation of the bacterial population in accordance with the DIN EN ISO 11737-1. After insertion of 9.3×10^9 CFU (colony forming unit) of *B. atrophaeus* on average into the measuring system, 99.9999973% of these were stopped by the MicroGard II filter.

For the viral filtration efficiency a cross-contamination rate of 99.979% was achieved using a high flow rate of 750 LPM⁵.

In two distinct setups, the daily use of the PFT equipment was simulated by³:

- **30 minutes of low flow (120 L/min = 2 L/s)** equivalent to the expiration in 60 minute tidal breathing as present in bodyplethysmography, N2 washout, He wash-in, diffusion, and slow spirometry
- **20 times at high flow (720 L/min = 12 L/s) for 5 seconds** equivalent to multiple flow/volume trials of 20 subjects



MicroGard™ IIB in pulmonary laboratory

The warm air supply and germ injection setup was validated to deliver a constant high amount of bacteria to the PFT equipment. After 90 and 180 working days³, the amount of bacteria in the PFT equipment was tested. The ratio between detected bacteria and infused bacteria was less than 0.001% in all tests and setups. More than 99.999% of the infused bacteria could not be detected in the PFT system.

The results of these bacterial filtration efficiency tests justified the prolongation of the reprocessing cycles for Vyaire PFT systems. MicroGard™ filters allows for a prolonged reprocessing cycle of parts downstream of the filter. Cleaning and high level disinfection is required only twice a year for many of the Vyaire PFT products. Please consult the hygiene manual for your device to determine the required interval.

Hygienic requirements during COVID-19

ERS:
Lung function testing during COVID-19 pandemic and beyond

"Test should always be carried out with a high specification disposable in-line bacterial and viral filter in place (We recommend filters with minimum proven efficiency for high expiratory flow of 600 to 700 L/min). Use of disposable combined mouthpieces/sensors is not recommended at this time. The exception would be where an additional filter can be added to the patient circuit and not degrade the measurements." ⁴

As a disposable in-line filter, MicroGard™ II meets the ERS requirements for the COVID-19 pandemic. The viral filtration efficiency of the MicroGard™ II filters was performed using the bacteriophage virus with a size of 0.027 microns as a surrogate. The COVID-19 virus is reported to have a particle size of 0.08 – 0.16 microns.



MicroGard™ IIB and IIC, disposable noseclip and mouthpiece

Filter material

The proprietary filter material used in the MicroGard™ is Microstat M190, a particular blend of polymers with a highly stable electrostatic charge. It consistently achieves high efficiencies by deploying both electrostatic charge as well as mechanical mechanisms to remove airborne particles. The high efficiency of the charged material allows for a more open matrix of fibers, resulting in a minimal restriction to the airflow. Most filtration materials use surface loading as the primary means of removal. With the material used in MicroGard™, the fiber matrix enables depth loading, where particles are captured throughout the entire filter material, not just on the surface. The polymer fibers impede the growth of mold mildew, fungus or bacteria. The filter material also is resistant to degradation over time and is able to withstand extreme temperature and humidity.

Controlled manufacturing

MicroGard™ II is produced in Germany using the highest quality materials, stringent manufacturing standards, and extensive quality control measured with annually re-validations. The Quality System at the manufacturing facility in Höchberg is certified to meet DIN EN ISO 13485 standard. The filter material has been tested for biocompatibility.

Lifetime simulation

Transport and storage validation tests showed that the MicroGard™ II filter maintains its filter efficiency and bioburden criteria over a lifetime of three years.

Conclusion

Based upon the scientific test results conducted by Nelson Laboratories, the MicroGard™ II filter proves to have the combination of greatest filtration efficiency with lowest resistance (Delta P) to airflow. Repeated multiple validation and verification testing show that the use of MicroGard™ filters does not compromise equipment measurement characteristics. To ensure correct measurement results, Vyaire respiratory diagnostics devices should only be used in combination with the precisely matched MicroGard™ filters. The use of MicroGard™ with these devices allows for prolonged cleaning cycles.



MicroGard™ IIB during N2 washout measurement

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