Cardiopulmonary Review

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.

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

Content

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

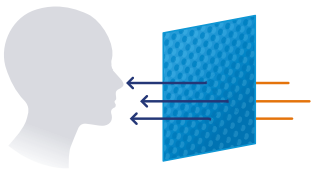
Efficiency versus resistance

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.

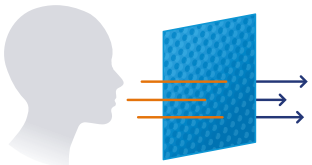
Bacterial Filtration Efficiency (BFE) and Viral Filtration Efficiency (VFE) are correlated to the basis weight of the filter media, which is also correlated to the flow resistance, referred as the delta P (ΔP). As the weight increases, the filtration efficiencies are higher and so is the delta P. The 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.

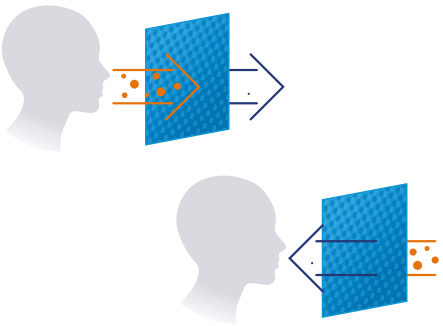
Filter resistance at various flows: MicroGard IIB (± 4%)			
L/s	L/min	kPa.s/l	cmH_2O
0.50	30	0.034	0.35
1.00	60	0.036	0.37
1.67	100	0.039	0.39
5.00	300	0.051	0.52
8.33	500	0.063	0.64
10.0	600	0.069	0.71
11.7	700	0.075	0.77
14.0	840	0.084	0.86
14.0	**840**	**ATS[4] max. 0.150**	**ATS[4] max. 1.53**



Inspiratory resistance:
<0.04 kPa/(L/s) at 1 L/s
(<0.4 cmH_2O/(L/s) at 1 L/s)



Expiratory resistance:
<0.04 kPa/(L/s) at 1 L/s
(<0.4 cmH_2O/(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 Vyaire 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 Chinese Food and Drug Administration (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 Vyaire PFT products it is used on. If a device of the Vyaire 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:

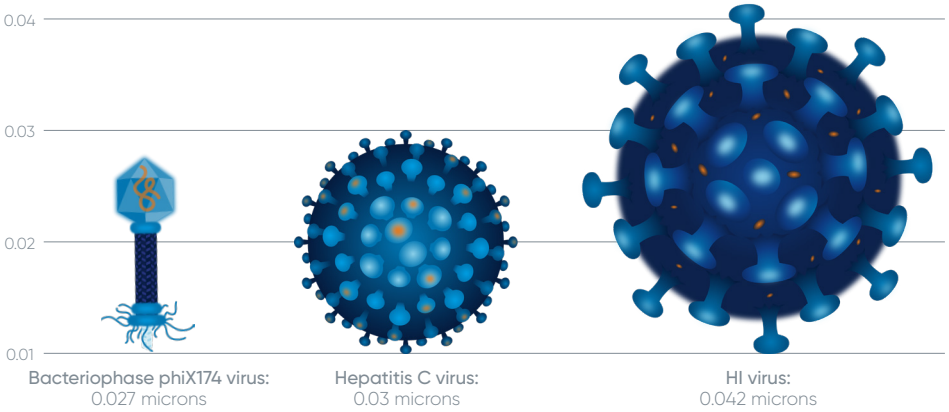
- correction of the filter's dead space
- correction of the filter's resistance for the measurement of specific airway resistance
- BTPS (body temperature, pressure, saturated with water vapor) correction to aide in stability and minimization of drift

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 removal efficiency tests using standardized operating procedures. The viral filtration efficiency testing was performed using the bacteriophage virus which, at 0.027 microns, is one of the smallest known viruses. It represents a significant challenge to the filter material due to its diminutive size and morphology.
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 Tuberculosis, by contrast, are much larger in size than viruses.



Size comparison of different viruses

Bioburden testing

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 0.0000027 % of B. atrophaeus on average into the measuring system, 99.9999973 % of these were stopped by the MicroGard II filter.
In two distinct setups, the daily use of the PFT equipment was simulated by:

- **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

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 days, 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 bioburden tests justified the prolongation of the cleaning cycles for Vyaire PFT systems.

MicroGard filters allows for a prolonged cleaning 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.

MicroGard IIB in pulmonary laboratory

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."[2]

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 0.027 microns. The COVID-19 virus is reported to have a particle size of 0.08 – 0.16 microns.

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.

MicroGard II is produced in Germany using the highest quality materials, stringent manufacturing standards, and extensive quality control measured with annually re-validations. Quality systems at the manufacturing facilities in Hoechberg are certified to meet DIN EN ISO 9001 and DIN EN ISO 13485 standards. The filter material has been tested for biocompatibility.[7]

MicroGard IIB and IIC, disposable noseclip and mouthpiece

MicroGard IIB during N2 washout measurement

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.

REFERENCES

1. Standardization of Spirometry 2019 Update. An Official American Thoracic Society and European Respiratory Society Technical Statement. American Journal of Respiratory and Critical Care Medicine Volume 200 Number 8, October 15 2019.
2. Recommendation from ERS Group 9.1 (Respiratory function technologists /Scientists) Lung function testing during COVID-19 pandemic and beyond
3. Nelson Testlaboratory has performed the following tests:
   - Filter I: Charge 31486-38, September 2013
   - Filter II: Charge 21, September 2013
4. ATS Standardization of Spirometry [ATS 2005, p. 332]
5. Nelson Report 10003754 - Viral Filtration Efficiency Test (VFE) at an Increased Challenge level GLP Report
   Nelson Report 10003754 - Bacterial Filtration Efficiency Test (BFE) at an Increased Challenge level GLP Report
6. Laboratories of senetics healthcare group GmbH & Co. KG has performed the following test in 2019:
   - Simulation of a daily usage of a spirometer with filter attachment for 180 calendar days
7. NAMSA has performed the following tests:
   - ISO Intracutaneous Study - Extract
   - Murine Local Lymph Nody Assay (LLNA) -(SC and DMSO Extracts)
   - Cytotoxicity Study Using the ISO Elution Method (1X MEM Extract)

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